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STATES OF CANCER IMMUNITY: THE ETHICAL DIMENSIONS OF HPV VACCINATION POLICIES

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Abstract.

Human Papillomavirus (HPV) is a sexually transmitted virus, recognized to be the necessary, yet not sufficient, cause of cervical cancer. Vaccines for individual administration targeting HPV are available today. In this dissertation I undertake a normative analysis of existing HPV vaccination programmes and evaluate how current policy alternatives put in balance competing moral concerns at stake. To this aim, I explore the ethical dimension of the different policy models, with respect to issues of respect for individual choice, expected coverage rates, and population health goals.

My goal is thus to show how the different policies - ranging from a hotly contested mandatory model to prima facie more justifiable voluntary approaches – fare with respect to the interests of individuals targeted by HPV vaccination campaigns. Differently from standard approaches in public health ethics, however, I show that concerns for individual choice in HPV contexts cannot be severed by equally important concerns for social justice. In particular, I show that an insistence on the least restrictive alternative alone leaves out of focus important concerns for social justice and the need to avoid the worsening of existing inequalities. Moreover, I argue that standard approaches in public health ethics should be widened to consider the legitimate interests of specific social groups, namely those belonging to socio-economically disadvantaged strata of society, and fair consideration of the health interests of minority groups.

In this dissertation I therefore present a rationale for adopting a capability-based approach to HPV immunization in order to cope with the most pressing ethical issues at stake in this field.

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Introduction. HPV at the crossroads of cancer research and prevention

Cancer is one of the major causes of death worldwide, the second behind only cardiovascular diseases. More than 7 million people died of cancer in 2008, and around 12.5 million individuals were diagnosed with the disease, accounting for nearly 14% of all deaths in that year (Ferlay et al. 2010). More than 7 million of the new cases occur in low and middle-income countries of the world, and these figures are expected to grow in the next few decades (Boyle and Levin 2008). Cancer is certainly a burden also in high-income countries. In Northern America and Western Europe, for instance, incidence rates of cancers at all sites are the highest both for men (334 per 100,000 and 335 per 100,000 respectively) and women (274 per 100,000 and 250 per 100.000 respectively)[1].

As impressive as those figures may be, they certainly do not fully convey the emotional and psychological toll of cancer on the life of many individuals and their families. One does not need to be a sociologist to be aware that much of these fears are accompanied by high societal expectation for new cures and treatments to come from biomedical research. The public attention on cancer, moreover, is not only apparent in the anxieties and hopes of citizens, but it is also manifest in the concerted political action and economic investments it attracts worldwide. Ever since the United States president Richard Nixon signed the National Cancer Act in 1971, a flood of economic investments and intellectual efforts has been directed to the understanding of the biological roots as well as treatment options for cancer. Four decades after this war –as it

[1] Incidence is the number of new cases arising in a given period in a specified population. It can be expressed as an absolute number of cases per year or as a rate per 100,000 persons per year (Ferlay et al. 2010). Throughout this work I will be mainly

is often described - was launched, the scientific community has made enormous progress at unravelling cancer's biology, delineating its fundamental architecture, and describing some of the finest details of its progression. The race to find new treatments and, possibly a cure for cancers, however, continues and more investment on research and prevention are still needed. As an example of this never decreasing effort, the Obama's administration presented the so-called 'Obama-Biden plan to combat cancer'. In his address to congress, in February 25th 2009, the President of the US claimed: "We will launch a new effort to conquer a disease that has touched the life of nearly every American, including me, by seeking a cure for cancer in our time… and it makes the largest investment ever in preventive care because that's one of the best ways to keep our people healthy and our costs under control"[2].

Cancer is a cellular disease consisting in uncontrolled cell growth and whose progression is organized stepwise. Major moments are: cancer initiation or formation (from normal cells to neoplasm), development (from a few neoplastic cells to a full blown tumour), and progression (invasion and metastasis). The term 'cancer' is a shortcut to refer to more than one hundred forms of the disease. Each tissue of our bodies has the potential to give rise to neoplastic malignancies. Each cancer, moreover, has unique features and calls for separate scientific investigation. Despite variation, however, it is now established in molecular oncology that every tumour pathogenesis can be conceptualized under a number of 'hallmarks of cancer', that is the shared organizing principles

[2] The plan can be found here: http://obama.3cdn.net/f8a8d6b8b4b370d888_24lmvygeu.pdf (last accessed: November 11th, 2011). Obama's speech can instead be found here: http://www.youtube.com/watch?v=3hXSzBOolLo (last accessed: November 11th,2011)

explaining neoplastic diseases progression. In a nutshell, the fundamental hallmarks are (Hanahan and Weinberg 2000; Hanahan and Weinberg 2011):

- the self-sufficiency in growth signals (cancer cells generate their growth hormones)
- the insensitivity to inhibition signals (cancer cells are deaf to signals of quiescence)
- the evasion of apoptosis (cancer cells do not die or go into senescence when they should)
- immortality (cancer cells replicate indefinitely)
- angiogenesis (creation of new blood vessels to bring more nutrients and oxygen to the tumour)
- invasion and metastasis (the cells invade the surrounding tissue and then spread to other body sites)

The increasing understanding of the biology of cancer, despite occasional scepticism, has helped improving survival rates of many patients in the last decades, and still offers enormous potential for the development of novel treatments and tools for early diagnosis. Detractors of cancer research sometimes question the practical success of these attempts, observing how little is the reduction of the total burden of cancers, both in the US and worldwide, as compared to the terrific intellectual and financial resources so far devoted to this crusade (Leaf 2004). In fairness, although it is true that the decline in incidence and mortalities for cancer in the US, and other economically developed countries, has not been as decisive as it was expected in the early

70's (nearly 10% decline in mortality from 1978 to 2005) it is also the case that our current understanding of the biology of cancer has increased exponentially, and with it the array of ways in which progress in therapies, identification of markers for disease early detection, and standards of care can potentially arise. In some cases, such as chronic myeloid leukaemia (CML), detailed molecular knowledge of tumour progression has been sufficient to help the development of effective treatments (Druker 2009; Lydon 2009). In others, however, more efforts are needed and the scientific community is currently engaged in finding ways to bring knowledge from the bench to the bedside, so to bridge the so-called 'gap' observed between basic and clinical research. The problem is certainly complex, and cancer scientists are actively engaged in identifying the main conceptual and regulative issues that may function as hindrances for progress (for a nice review about this problem see for instance: Moran 2007; Miller and Larionov 2011).

The increasing understanding of cancer, moreover, helped also to realize, not which much surprise however, that one of the best ways to combat this disease is by preventing it to occur in the first place. The *World Health Organization* (WHO), for instance, estimates that nearly one third of all cancers could be prevented by appropriate policy actions, and some argue for a public health approach to win the war on cancer (Frieden et al. 2008). For instance, cigarette smoking is now recognized to cause nearly 70% of lung cancers, and it is involved in the etiology of nearly 30% of all cancers (Vineis et al. 2004). Epidemiological evidence, moreover, is showing also how other life-styles can have a huge impact on cancer rates worldwide. Obesity, for instance, is thought to be correlated not only with diabetes and coronary diseases, but also with a

number of cancers of the endometrium, kidney, breast, and esophagus. It has been estimated that in the US, if the prevalence of overweight and obesity were reduced, about 90,000 deaths per year could be prevented (Calle et al. 2003). Healthy diets and physical exercise, moreover, are also associated with positive outcomes in terms of cancer prevention. The WHO (2004) reports that a suitable increase in fruit and vegetables consumption could prevent world wide 5-12% of the total cancer burden. Besides numbers, however, the focus on prevention does not only require a shift in individual behaviour, but also dedicated patterns of policies and regulations that can create suitable environments for correct preventive practices to take place. Bans on cigarette smoking in public spaces, as adopted in several countries, are but one of possible policy options that can make a difference in the prevention of cancer and other diseases. Being cancer a global burden, the WHO has launched a number of initiatives to urge governments to adopt policies that:

a) monitor tobacco use, protect people from tobacco smoke, offer help to quit tobacco use, warn about the dangers of tobacco, enforce bans on tobacco advertising, promotion and sponsorship, raise taxes on tobacco (WHO 2011)

b) foster a favourable environment for the exercise of individual responsibility for health through the adoption of lifestyles that include a healthy diet and physical activity (WHO 2004)

Research and prevention need not to be put in opposition. Both have their merits and promises benefits. None of them, however, is unproblematic. Research, on the one hand, promises benefits in terms of new treatments and therapies, which should improve prognosis of patients once they get ill. It is,

however, a painstaking activity with no negligible intellectual and financial costs for the community. Prevention, on the other, is economically less expensive, but less so in terms of the policy action it requires in order to build the right social architecture, and bring about changes in individual behaviour.

Though not adversarial the two perspectives indicate how the global effort to defeat cancer is set with major complications requiring a plethora of intellectual, financial and, not less importantly, cultural actions, none of them being unproblematic. At times, however, scientific ingenuity fully justifies decades of research efforts and provides biomedical innovations that add a significant piece in the complex puzzle of cancer control also at the clinical level. From 2000 to 2009 the Food and Drug Administration, the US authority that approves drugs for introduction on the medical market, licenced 62 oncological drugs[3], each with significant prospects for the treatment of cancer patients (Simon 2010). Among them, two products posses the features of truly medical breakthroughs for the impact they may have on individuals' and population health: Gardasil (2006) and Cervarix (2009). Also authorised by the European Medicines Agency (2006 and 2007 respectively), Gardasil and Cervarix are vaccines for individual administration targeting those types of the Human Papillomavirus, a sexually transmitted virus, which are now recognized to be the necessary, yet not sufficient, cause of about 70% of cervical cancers worldwide (Walboomers et al. 1999). HPV, as it will be shown more extensively below, is causally connected not only with cervical cancers but, as it is progressively appearing from recent epidemiological studies with other kinds

[3] Drugs approved by the FDA can be searched at the agency's website, more specifically, through the search of the database to be found at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu (last access: September 1st, 2011)

of neoplastic malignancies and other morbidities. The burden of cervical cancer, however, is the most significant in terms of annual incidence and mortalities, among all the HPV-related diseases.

Cervical cancer, is a neoplastic malignancy arising in the cervix uteri, and is the third most common cancer in women worldwide. The *International Agency for Research on Cancer* (IARC) estimates show that in 2008 about 530,000 women were diagnosed with this disease, and about 275,000 women died in the same year (Ferlay et al. 2010)[4]. The burden of cervical cancer is most apparent in developing countries, where about 85% of the new cases occur. In developed countries, instead, decades of preventive methods, like screening of the women population for cytological abnormalities that precede cancer (the so-called Papanicolau test), led to a decline of the incidence of new cases. Nevertheless, cervical cancer remains among the most common cancer of women also in these areas. For instance, IARC's Globocan research identified about 83,000 new cases occurring in the most economically advanced areas of the globe every year. Cervical cancer thus is the seventh women cancer by incidence in these areas. Although the striking difference existing between most and less economically developed areas of the world, cervical cancer is still a major problem for women in the higher-income countries too. The burden of this disease for society is accentuated even further if we take into account the average age at diagnosis and death. In this case, cervical cancer is the second most common cancer among women aged 15-44 in Europe. Cervical cancer is hence among the

[4] Throughout this chapter, and wherever I cite cancer related statistics I would refer to the estimates provided by GLOBOCAN project. GLOBOCAN is a WHO and IARC joint software that provides facts and figures about cancer incidence and mortality worldwide. It can be find at: http://globocan.iarc.fr/. Where different sources will be used I would cite them accordingly.

tumours that mostly impact on younger women in a stage of life in which much of their familial and personal projects are still developing.

At a glance, HPV vaccines offer the reassuring features that arguably anyone expects from biomedical innovations. With three injections, to be administered over six months prior to sexual debut in young girls, HPV vaccines confer protection against those infective agents that, if encountered, could lead to development of such a terrible disease. If one, moreover, thinks about the health impact that these innovations may have if administered on a population scale, claims for significant public health progress would be more than justified. Clearly, it can also be admitted, this advancement constitutes only one small battlefield victory in the war against what it has been defined the emperor of all maladies (Mukherjee 2010). Nonetheless, HPV vaccines seemingly vindicate the promises of decades of scientific research efforts, and they do so by tackling the disease before it occurs. 'One ounce of prevention is worth a pound of cure' popular wisdom says. In the case of HPV vaccines, it could be thought, that very 'ounce' appears even lighter if compared to other cancer preventive methods. HPV immunization, in fact, offers the simplicity of all vaccines; it prevents disease without the need to change much about one's lifestyle.

Having this seemingly enthusiastic words been said, one could wonder what it is then problematic about HPV vaccination. Isn't it a paradigmatic example of how the outcomes of scientific progress should look like? Isn't it a great achievement in cancer prevention? Although HPV vaccination offers great medical benefits, its implementation is not devoid of complexities and ethical problems. Namely, the achievement of sensible population health goals with respect to immunity generates problems of autonomous individual choice and

distributive justice. It has indeed to be noticed that the choice of distributive strategies may attain different coverage ratios among differently situated social groups, as I will show throughout the thesis. In particular I will argue that problems of autonomy and distributive justice are particularly thorny with respect to three axes: individual choice versus population health; individual choice versus justice; gender equity versus efficiency. Addressing these problems, I argue, is of paramount importance to build up this innovation as a socially robust advancement. The problems that I will highlight, it must be noticed, are not technical but moral. In other terms, for a new technology to be proper advancement it has not only to overcome those obstacles that sometimes may slow down or impede its implementation. The latter may be: problems of budgeting, problems pertaining to the delivery of the new products, problems of communication with all stakeholders, problems in creating new expertise, and the like. All these are certainly interesting issues, but all are more properly addressed from the perspective of public health policy science (Hunter 2003; Buse et al. 2005). I will instead address from an ethical perspective the conditions, if any, which make HPV vaccination desirable and the ethical trade-offs, if any, that need to be put in balance for its policy implementation. In other words, although it can be easily conceded that putting in place public HPV vaccination policies may be ethically justifiable given the burden and severity of the disease they can contribute to control, it remains to be seen what the appropriate means for achieving that goal are.

This thesis is thus devoted to the ethical examination of public HPV vaccination policies as recently implemented in several developed countries[5]. Taking HPV vaccination policies as a case study allows me to discuss what I consider important issues in public health ethics in general. The basic problem I will face is that of finding a balance, though provisional, among equity concerns, efficiency and individual choice. All these three aspects have important moral weight that needs to be balanced according to different contextual needs and depending on the case at hand. Connected to these issues there is the problem of the role that the state has to play in funding and promoting the different programmes and how it deals with the abovementioned values.

For reasons of methodological clarity this thesis is divided in two parts. In the first part I will provide the theoretical background that will inform the analysis of the case study in the second part.

In chapter 1 I will start with an overview of the discipline of public health ethics. I will first present what I take to be the received view of the discipline, what I call the beneficence model of public health ethics and then challenge some of its assumptions by the means of some concepts of republicanism as a political philosophy. In particular, I will contrast their conceptions of 'freedom' and how they relate it with populational concerns.

In chapter 2 I will enlarge the scope of my analysis to issues of distributive and social justice and see how they can be framed in public health ethics. I will specify, in that context, that socially determined health inequalities are of

[5] The choice of developed countries does not derive from a lack of interest towards issues of global justice, but are motivated but is motivated by my background theoretical interests in analysing the moral relationship existing between the state and its citizens.

particular moral importance. For this reason, I will provide a minimal requirement of justice that public health policies need to satisfy. I call it the negative aim of justice, and it is an injunction for public health policies not to worsen existing inequalities. This point will become important in the context of the normative comparative analysis in chapter 4. In chapter 2 I will also show that public health ethics should not be blind as to the elaboration of what public health policies should aim at. I will thus present Sen's capability approach as a good candidate at elucidating this task. The presentation of this approach will become important in the context of the concluding chapter of this thesis (chapter 6), where I will show that the focus in HPV vaccination policies should be on maximising capabilities rather than merely aiming at achieving high coverage rates.

In chapter 3 I will present the biological and epidemiological background of HPV and related disease burden and how an emerging political debate is highlighting the morally and socially relevant dimensions of HPV vaccination campaigns.

In chapter 4, I will present a normative comparative analysis of current HPV policy proposals. This analysis will draw on the conclusions of chapters 1 and 2 and will further expand them to show that the concerns of justice and individual freedom are not appropriately captured by the received view in public health ethics.

In chapter 5, I will introduce moral reasons to expand the vaccination policies to the male population despite such an option is not usually deemed to be cost-effective from an health economic point of view.

In chapter 6, finally, I will argue that our ethical gaze can be expanded if HPV vaccination takes the capability-distribution approach at face value. In this

respect, I will maintain that by adopting a capability-oriented approach to the design of HPV vaccination policies is of substantial advantage to tackle problems of justice, fairness and inclusion.

Part 1: Theoretical framework

Chapter one: Individual choice and the common good. The ethical dimension of public health

1. Introduction: the discipline of public health ethics

The aim of this and the following chapter is to set the stage for the normative analysis of Human Papillomavirus (HPV) vaccination programmes in the remainder of this work. I will introduce the main ethical issues arising from public health activities and different attempts at their solution recently proposed. The outline I propose is functional to the discussion I will set out in the remainder of the work and it is focused on those problems that are of particular importance from an ethical perspective and that lend themselves to treatment by the means of theories or approaches in philosophical ethics or political philosophy. Since the remaining part of this work will be devoted to the analysis of a case study, the themes of this and the subsequent chapter will be discussed in an abstract way, and examples of specific public health activities will be kept to a minimum. It may be worth underlining though that they will not arise in this general form but will be embedded in specific substantive questions about what to do in a specific circumstance.

Public health ethics, as a disciplinary endeavour, stems out of the broad field of bioethics as an attempt to broaden the scope of its agenda (Verweij 2000; Cribb 2005). If the focus of traditional approaches in medical and research ethics is the analysis of morally problematic issues occurring in the clinic or in specific research settings, public health ethics turns its attention to

those activities aimed at preventing morbidity and promoting health at the population level.

Bioethics has long been concerned with issues arising from the interaction between individual patients and health care professionals. The much praised, as well as hotly contested, *Principles of Biomedical Ethics* (Beauchamp and Childress 2009) are probably the most representative, but by no means unique, outcomes of decades of philosophical engagement with morally sensitive problems arising from doctor-patient encounters. Although it is not my intention here to give a detailed historical analysis of bioethics in all its forms, it is useful to remind how it grew out of a close relationship with legal theory in reaction to the paternalistic models of clinical encounters that were dominant at least until the late 1950s. This collaboration, fuelled by broader social concerns about individual liberty and social equality - demanding also more appropriate standards of respect in health care - has given shape to the legal theory of informed consent and an extensive elaboration of its philosophical underpinnings, epitomized in the principle of respect for autonomy (Faden, Beauchamp, and King 1986, p.87). Arguably, the principle of respect for autonomy is not only an abstract guide to professional ethical thinking, but also a fundamental value of democratic societies. In this vein, bioethics, in both its research and medical ethics forms, has hence focused primarily, though not exclusively, on respect for autonomy, its conceptual clarification and the contextual challenges to its implementation arising in specific clinical and research settings. Whether this conception fully encapsulates the ethics of clinical encounters is disputable (Gert, Culver, and Clouser 1997); it is general consensus though that it fails to capture the ethical

dimension of public health activities (Holland 2007a; Wikler and Brock 2007; Dawson 2010)

The initial thrust of public health ethics consists in identifying what issues, if any, are specific to public health, and whether the classic vocabulary of bioethics is adequate for them. For instance, some argue that bioethics has been the victim of an obsession with autonomy, and an appropriate ethical analysis of public health policy should be able to go beyond autonomy and explore different values, like solidarity, responsibility, and equity to mention a few (for one example see: Dawson 2010). Others insist that public health ethics should be mainly a justificatory activity, and it should provide consistent frameworks of principles that serve as a guide for a morally acceptable implementation of specific policies (Upshur 2002). Overall, it is generally agreed that public health is most clearly justified when it produces shared goods that cannot be shared out that is - in the language of classical welfare economics - when it brings about public goods (Verweij and Dawson 2007; Gostin 2008; Anomaly 2011).

The sometimes conflicting needs of individuals and populations, is said, call for an opening up of the bioethical agenda, the latter being often understood in terms of a dyadic relationship between health care professionals and individual patients implying specific duties and rights on the two sides. One way of presenting ethical issues in public health, instead, is in terms of a problematic triad (Holland 2010). The entities composing this triad are the government proposing a public health initiative, the individuals who have to comply with the initiative, and the population to whose benefit the intervention is originally proposed. A scrutiny of the ethical dimension of public health activities requires a conceptual shift from the domain of health care to that of

health broadly conceived, from single medical interventions on identifiable individuals to a set of policies targeting populations (Cribb 2005). In this context, a shift is needed also in the language and in the sensitivity of ethical analysis. To describe this shift in figurative talk, Wikler and Brock (2008) call for a new bioethics adopting a bird's eye view that looks at populations rather than solely at individuals. The bird's eye perspective nicely illustrates the concerns of population-level bioethics. The latter should investigate not only health care and its delivery, but also broader social determinants of health, like socio-economic status, working and environmental conditions, and social exclusion. Arising from these considerations it becomes clear how the normative sources of bioethics and public health ethics differ. The former draws on moral philosophy and other sources of reflection on values, the latter relies chiefly on theories of social justice and political philosophy (Wikler and Brock 2008, p.15). This specification, however, does not simplify the matter. Already in the 1990s novel perspectives in medical ethics emerged challenging the mainstream principlist framework (Davis 1995). These included feminist care ethics (Tong 1998), social science perspectives (Weisz 1989; Hoffmaster 1992; J. H. Evans 2000) casuistry and historical critiques (Cooter 1995), as well as broader perplexities about its technicization (J. H. Evans 2002). The diversity of these approaches shows us that medical ethics cannot be reduced to one single framework, despite its success and usefulness in some contexts. In the same vein, public health ethics cannot be reduced to one single framework, theory or approach in political philosophy. Different approaches, in fact, would licence or censor different policies by emphasizing the priority of different values. In the remaining paragraphs, I will survey this complexity by showing the scope of some key concepts in public health ethics. To do this I will explore

how analysts from two different theoretical persuasions would address fundamental issues in public health like: 'what are the aims of public health?', 'What kind of good is public health distributing?', 'Is there a trade-off between liberty and public health?'. By doing this I do not want to adjudicate among any of them at this stage, and hence – although I will express my preference for one approach - adversarial language will be kept to a minimum. Nevertheless, this effort is useful to provide a repertoire of frameworks and concepts for the ethical analysis of the case study.

Before starting to explore the ethical dimension of public health ethics it is necessary, for reasons of methodological clarity, to distinguish what is meant by terms such as 'public health' and 'population health'. Clearly, this is not easy task. Nor it is specific goal of this work to provide a definite and uncontroversial conceptual analysis of these terms and expressions. I will, however, attempt to disambiguate those terms and show how I will use them throughout this work.

Let us start first with a clarification of the way I intend to use the cognate expressions 'public health' and 'population health'. Throughout this work I will use the former by and large following the Institute of Medicine (IOM)'s (Institute of Medicine 1988) landmark definition: "Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy." This definition advocates the need for cooperative behaviour and assumes the existence of relationships established on overlapping values among different social actors. In this sense, 'public health' is not a purportedly objective state of supra-individual health, but a set of activities, policies and interventions performed by: a range of governmental, private and non-profits organizations, professionals from different fields, and citizens. The IOM's definition, clearly,

does not specify who is the 'we' that should guarantee the conditions for health. I assume that the social actors just identified are good candidates for the task. Accordingly, the role of public health ethics is to identify whether there are special obligations among those different entities. I will expand on this below where I will tackle directly the question about the aims of public health. For the moment let us proceed with the specification of the terms I am using.

With 'population health' I will refer to accepted, revisable, contested claims about the health of a given population. These claims are generally provided as answers to questions such as: What is the incidence of disease X in population Y? According to how 'health' is understood or measured, the status of population health may differ. For my current purposes, however, it is sufficient to say that population health is what public health policies aim at. Public health ethics is thus a normative analysis of policies and initiatives with a population perspective. Saying this by no means imply that the way populations, or target groups, are picked up as objects of public health interventions is normatively neutral; nor that there is an objective status of population health unambiguously calling for public health intervention. On the contrary, these choices carry with them value assumptions and ethical implications. It is thus the role of public health ethics to identify what they are and provide guidance, within the limits proper of philosophical theories, as to their analysis.

2. The beneficence model of public health ethics

These clarifications having been made, let us now think about how one should conceive of the aims of public health initiatives. In this section, I will present what I call, following (Powers and Faden 2006), the benefice model of public health ethics. As Powers and Faden notice, the ethical analysis of public

health activities is, most of the times, thin (2006, p. 9). The standard view in public health ethics sees public health as the social institution aiming at the advancement of human welfare by bringing about a certain kind of human good, the good of health. The moral underpinning for public health is thus a general obligation in beneficence to advance welfare. Interpretations may then vary, and public health may have a further utilitarian commitment to bring about as much health as possible. This general formulation is epitomised in several passages in a seminal paper in the field: "Several […] moral considerations – especially benefiting others, preventing and removing harms and utility - provide a prima facie warrant for many activities in pursuit of the goal of public health" (Childress et al. 2002). In the beneficence model, concerns about justice and respect for individual liberties are thus understood as exterior to the practice and commitments of public health, and they "serve to balance public health's single minded function to produce the good of health with other, right making concerns" (Powers and Faden 2006, p. 81).

This model emphasizes that the primary goal of public health is devising and implementing programmes to maintain or improve population health by preventing disease and disability and promoting health. Although the ultimate goal is to save real lives and help real people, its success is measured in terms of statistical lives and decrease in the incidence of disease. Specific types of public health initiatives include mass immunization campaigns, screening programmes and the various interventions loosely aimed at health promotion. Public health promises benefits in terms of the health of target populations, at a cost to individuals. The cost varies from context to context, and may include: participation to a mass immunization campaign, to join in a screening

programme, or adopting healthy life-styles. The population perspective typically adopted in public health initiatives requires a, more or less, strong governmental intervention as to ensure widespread public participation to the specific programme at hand. High compliance with public health initiatives is, in fact, fundamental to observe significant results in terms of disease reduction at the population level. The extent of governmental, or state, involvement in the promotion of public health campaigns may also vary depending on the context; it ranges from promotion of so-called healthy behaviours through public educational campaigns (such as those encouraging people to exercise), through more intrusive initiatives aimed at avoiding unhealthy habits (such as cigarette smoke or fat-rich diets), up to coercive measure requiring, for instance, mandatory vaccination for children upon school entrance. Moreover, social epidemiology is progressively ascertaining how diverse social and economic circumstances play a role at determining one's health status (Marmot 2004). These findings drastically enlarge the scope of possible government's activities as to preserve health up to broader interventions aimed at ameliorating the social environment in which unhealthy behaviours are found to take place or, more profoundly, at a more equal redistribution of primary social goods (Daniels 2008, especially pp. 79-102) .

The beneficence model of public health ethics recognizes that attention for population health is important. Nevertheless, it also acknowledges that public health activities may be problematic from an ethical perspective in that they potentially interfere with individual liberties and ways of living. One standard argument for the justification of interference on the liberty of individuals, one accepted by many political philosophers, including those of

libertarian persuasion, is the famous and often cited harm to others principle proposed in 1859 by John Stuart Mill in his *On Liberty*, where he says:

> That the only purpose for which power can be rightfully exercised over any member of a civilized community against his will is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot be rightfully compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinion of others to do so would be wise, or even right. (Mill 2003)

The harm to others principle can be used to justify some liberty limiting public health policies – like bans smoking bans in public places on the ground of the harmful effects of passive smoking – but not to all. Although the harm-to-others principle enjoys widespread acceptance, its application is not wholly uncontroversial, in that it is not easy to provide definite criteria as to what counts as a harmful action. For one, it is not clear whether harmful actions necessarily involve forms of physical damage, or that the harmed subject is made worse off by them (Feinberg 1987). In some accounts, one is genuinely harmed also when he is prevented to get what he deserves or improve his condition (Raz 1986). The applicability of the harm principle is thus not straightforward; I will give an account of this intricacy in the context of the case study of this work in the next chapter.

This complexity notwithstanding, problematic trade-offs in the beneficence model of public health also arise from the clash between the utilitarian call for maximization of benefits and the liberal emphasis on individual liberties or, in other words, between public good and private interests. In the beneficence model, individual rights to freedom, understood in

the form of non-interference from powerful institutions, can be sometimes overridden when they further the public interest defined in at least two forms: maximization of utility (in the public health case of health outcomes), and public goods *strictu sensu*. For a better appreciation of the latter notion some specifications are in order.

Public goods, in the technical sense elaborated by welfare economists of the 1950s, are those goods that are non-rival and non-excludable. The non-rivalry property indicates that the consumption of the good by an individual does not subtract from any other individual's consumption of the same good (Samuelson 1954); the non-excludability property implies that no one can be excluded by the consumption of the good. Typical examples of public goods are clean air, national defence, and public education. All the listed goods are for the enjoyment of all, and it is not possible to rightfully exclude anyone from their benefits. Some public goods, moreover, enjoy a third fundamental feature; they are dependent upon cooperation in that their provision would be threatened if left to private initiative. In the beneficence model of public health ethics, the creation of public goods is what most clearly justifies public interventions and interference on the private lives of citizens, at least so under certain conditions that I will specify below. One notable example of public good, especially from the perspective of this work, is herd immunity as provided by vaccination programmes. Herd immunity is the epidemiological phenomenon that occurs when a high proportion of individuals within a population are immunized against an infective contagious agent so that the transmission of that agent effectively stops (Fox et al. 1971). Mass immunization programmes have the potential to bring about herd immunity by raising the general level of immunity

in the population and rendering less likely an epidemic outbreak. The number of people needed to reach herd immunity thresholds varies according to the infectivity of the agent, its incubation period and the structure of the population (*ibid.*). In general, the highest the infectivity the highest is also the number of people that need to be immunized to generate herd effects. For instance, it is calculated that herd immunity for measles obtains when 90-95% of the relevant population gets vaccinated (Fine 1993) Herd immunity, once created, protects the population as a whole also those that, for any reason, couldn't be immunized or were immunized but did not develop appropriate immune response. In this respect, herd immunity has been defined as a public good (Dawson 2007). Indeed, it possesses all the features outlined above. It is non-rival - my 'consumption of herd immunity' does not subtract from yours - and it is non-excludable – once in place, no one can be excluded from its benefits. Moreover, herd immunity requires collective action for its creation. A number of ethical problems have been raised with respect to herd immunity. For instance, if there is an individual obligation in participating in those programmes aiming at its achievement (Dawson 2007) or if, once it is in place, those who are not contributing at maintaining it are morally blameworthy on the grounds that they are free-riding on a public good (Dare 1998). More generally, one of the main questions in public health ethics – and in this work - is the following: how do we determine whether the achievement of a particular public good can justify infringing upon individual liberties?

In order to answer to this question, many scholars have developed detailed frameworks that are supposed to capture both the goals and the general moral considerations informing public health practice and the

conditions the latter should meet in order to respect competing concerns for individual liberties. In this approach the role of analysts in public health ethics is a kind of balancing activity between the demands of population health and individual interests. According to the circumstances, then, the applied philosopher should assess whether in a given public health intervention priority should be given to the rights and the needs of the individuals, or to the benefits the intervention would bring about to the community. In general, a public health intervention is more easily justified when the population benefits are great and the infringement of individual liberties minimal.

One important requirement mentioned in the various frameworks is the effectiveness of the intervention (Kass 2001; Childress et al. 2002; Upshur 2002; Gostin 2008). Accordingly, the justification of a given a public health initiative requires evidence that the initiative is both necessary and effective at tackling the population health problem identified. In the words of one of the proponents of this requirement: "[Since] proposed regulation entails personal burdens and economic costs, governments should affirmatively demonstrate through scientific data that the methods adopted are reasonably likely to achieve the public health objective" (Gostin 2008, p. 63). A further condition in the beneficence model - one that is of paramount importance in the context of this work - and that is present in all the accounts cited above, is variously called the least restrictive alternative, least coercive means or least infringement. The idea behind the 'least restrictive means' condition is that in today's affluent societies the array of public health measures and preventive options offered to individuals is steadily increasing as epidemiological findings about disease specific risk factors pile up and new biomedical technologies (new drugs, or

new diagnostic tools) are introduced into the market and healthcare system. The latter, besides creating a prima facie opportunity for all those willing to preserve their health, can give rise to worries related to the progressive erosion of individual liberties once governments increasingly try to stir people's preference towards the adoption of healthy life-styles, or encourage them to join preventive campaigns with the aim of maximizing population health. In a nutshell, those who are concerned with individual liberty as a fundamental value of liberal democratic societies can look with suspicion at public health interventions taken singularly, as for instance bans on smoking in public spaces, or as a whole, in terms of a progressive identification of the good life with the healthy life. The more extreme among these formulations is probably one by the late Jonathan Mann who, in the context of the AIDS epidemics, wrote: "For the present, it may be useful to adopt the maxim that health policies and programs should be considered discriminatory and burdensome on human rights until proven otherwise." (Mann et al. 1994) In the context of the beneficence model, this means that public health agencies should adopt the policy that is most likely to prevent disease as effectively as other alternatives, while incurring the fewest possible personal burdens. In the context of my analysis of the HPV case I will show that insisting on the idea of the 'least coercive means' or 'least coercive alternative' does not fully encapsulates the ethical dimensions of public health policies and, in particular, of HPV policies. I will show, more specifically that concerns for justice may challenge this idea. For the moment, however, we can conclude this section by saying that the limiting conditions of public health activities just outlined serve, in the beneficence liberal model, as an ethical safeguard to keep to a minimum public invasion of the private sphere.

3. Common health goods in a republic

The beneficence model so far described epitomizes the effort of constructing a revised liberal framework for public health. The limiting conditions of the various frameworks, of which I have cited the most present, are an attempt at this direction. Nevertheless, other traditions critical of distinctly liberal approach, especially in its libertarian form, have been put forth as particularly fit to the exploration of the ethical dimension of public health activities. Of relevance for the purposes of my analysis are those critiques coming from republican philosophical tradition. In this section, after a brief outline of the central tenets of this political philosophy, I will concentrate on the republican formulation of 'common good' and assess whether it is a good candidate for enlarging the scope of public health's aims.

Although philosophical republicanism - to not be confounded with the political party in the US with the same name - has a long history, for large part of the last century was sitting at the margins of political philosophers' attention. By the 1990s, however, it had a revival (Pettit 1999; Skinner 1998), and it has been recently proposed as particularly fitting to the purposes of public health (Callahan and Jennings 2002). Recent republican political philosophy arose in opposition to liberal conceptions of freedom and individual rights intended as a form of protection from political interference. To philosophical republicans the notion of liberty most suited, both descriptively and normatively, for political life is freedom as non-domination or, in other terms, freedom as absence of arbitrary interference in the free choices of the free person (Pettit 1997, p. 271). Domination, on this account, is the imposition of one's will on another. Domination can emerge not only from governmental institutions, but also from

other groups in society. Arbitrary interference is key in this context. To republicans a non-interfered agent is not necessarily free, the classic example being the relationship between a slave and his benevolent master. At some time point the slave can actually be free from interference, but his status is dependent on the caprices of the master. Interference is thus not morally dubious as such, but only when it is exercised as a form of domination. Effective freedom only exists, for republicans, when to each individual belonging to a community is recognized equal membership, standing and respect, and in absence of influences from arbitrary power. Rights claims in republican thought thus are not claims of freedom from interference but, more extensively, claims for full and equal civic membership. In this respect, public health policies that may sound as morally suspicious for liberals, for instance policies restricting unhealthy behaviours such as smoking, are not necessarily so to republicans; at least as long as these policies track individuals recognizable interests and emerge from vibrant civic engagement in the definition of common goods and shared interests.

The common good, on this account, shares some features with public goods as defined above, but it is more far-reaching than them. The notion of common good as it comes out from republican tradition, in fact, does not necessitate instantiating those formal properties that are typical of public goods in the welfare economists' sense. The non-rivalry and non-excludability properties of public goods indicate that those goods are provided to the collective and, once in place, no one can prevent others benefiting from them. Although most of the times 'public goods' are publicly produced, it is not necessarily the case. We can imagine, for instance, a group of citizens

collaborating to ameliorate the streets of their neighbourhood. Once renewed, everyone - also those who did not contribute to the realization of the project - will be able to drive through the streets, in this sense a public good has been produced through private means. Most of the times, however, public health goods, like infectious disease control, need public intervention to be effective at a population level. In these special cases, hence, public goods are so both for the non-rivalry and non-excludability properties, and for being produced through public efforts.

If we come back to the comparison with common good, though, we realize that the value of public goods does not depend so much on the fact that we have them in common, but that, when produced either by private initiative or concerted action, they benefit all. One can imagine of public goods as goods that, although sometimes collectively provided or protected, can be decomposed in discrete units of consumption. It is the latter, at least on a liberal understanding, which gives value to them. In contrast, the value of the common good is inextricable from what makes it common. As exemplified by Alexander (2010, 18), an analogy with the idea of common good is friendship. What it is important about friendship is not the fact that involves more than one individual; in this sense, many non-common goods require more than one person for their enjoyment. What makes it valuable is its intrinsic commonality, the very fact that it cannot be decomposed to individual occurrences for private consumption. The notion of common good, to be precise, is conceptually separated from the very idea of consumption. It is, instead, a different framing of the relationships occurring among individuals, pointing towards their social embeddedness and to the irreducibly social character of goods arising from

some of these interactions (Taylor 1995). To elaborate a little bit further on this point, let us see in what other ways the approach so far described differs from the beneficence model.

The language of the beneficence model is one of interests and utilities, in its utilitarian side, and of rights and liberties in its liberal underpinnings. Potentially liberty-limiting state actions are subject to an assessment of means-ends rationality, risk-benefit ratios, and the balancing of individual rights of self-determination with obligations of self-restraint. The limiting conditions outlined above perform exactly this balancing role between the free-choices of individuals on the one side, and harm-prevention, to self and others, on the other. The public interest, in its form of public good or maximization of population outcomes, serve as an instrumental objective of public policy and individuals are imagined to have only external relationships to those interests. On the contrary, for scholars of republican orientation, the common good is not instrumental in any meaningful sense, for it is nothing but the good internal to the exercise of civic virtues. As Jennings claims: "The common good is constituted by the proper institutionalization and functioning of citizenship and by the proper embedding of civic virtue in the life world." (2007, 47) As Pettit specifies, a common good can be identified when it can be determined as people's 'common avowable interests'. The common good is hence equivalent to the common interests that people have qua citizens of a given polity. Those interests are, 'avowable' if are either conscious or if can be easily brought to consciousness upon reflection. They are, moreover, common insofar as cooperatively admissible considerations support their collective provision (Alexander 2010, 18).

In the context of public health, for instance, one could say that we all have a common interest in living in a society that regulates risks that are shared by all. Moreover, we all benefit in living in healthy and safe communities. This would amount, among other things, to put in place a stronger community life, enhanced social relationships and a more productive workforce. These elements constitute an advantage for any member of the society beyond his or her narrow interests in the public health intervention itself. In some instances hence, curtailing individual choice would not be seen as problematic in this approach.

The problem with such a normatively resonant notion of the common good is that its implications for health policy analysis cannot be easily cashed out. Bayer and Fairchild, for instance, write:

> We begin with the conviction that at the core of public health practice is the charge to protect the common good, to intervene for such ends even in the face of uncertainty. This stance may, we believe, necessitate limits on the choice of individuals on grounds of communal protection against both hazard and paternalism. (Bayer and Fairchild 2004, 488)

On the one hand, the protection from common threat has an important ethical dimension in that it benefits every member of a given community. The possibility to achieve a state of affairs to the benefit of all alerts us that individual autonomy is not necessary a trumping card against all other values – requiring instead accurate balancing. On the other hand, exactly because the common good is such a powerful concept, one must be wary as to how it is employed and whether the interventions that are, from time to time, proposed as priorities by public health departments are actually understood and

subscribed as such by the people who will be affected by the intervention. In other words, one should also be wary of committing the opposite mistake and make of the common good, without further specification, the mantra of public health ethics. In other terms, not every public health activity is immediately justified by the fact that it is public and aims at population health. Nor, the achievement of common good identified as population health should necessarily imply that moral interests of the individuals who are asked to comply with public health interventions do not deserve due attention and respect.

Nevertheless, the notion of common good may prove useful in terms of how public health policies should or can be framed. Jennings, for instance, urges us that the more issues are framed in terms of a contrast between two poles, population on one side and individuals on the other, the more public health will be experiences of suspicious competitive egoism and cynicism. In this respect, public health interventions would prove ineffective if left to voluntary participation or too costly and repressive if instantiated through coercive means. Arguments to support public health should instead "appeal more concretely and specifically to ideals and feelings engendered by people's lived experience in various social practices." (Jennings 2007, 57) The trade-off between individual rights and population needs would perhaps persist, but it is only through the creation of a political space and a political imaginary, that it would be possible to constitute a common good. In the case of public health, it would then be necessary to create a space for a shared perception of what is a common benefit or threat.

Much of the work in public health ethics, however, appears to have misinterpreted the idea of common good as it comes out of the republican tradition. In the latter, the common good is the regulative ideal constitutive of the practice of free citizenship in a free republic. It is the absence of arbitrary power relationships, not an instrumental objective for public policies. Once the potential for arbitrary influence is eliminated, then interference on individual choices for protecting common avowable interests would not be morally problematic nor liberty diminishing *per se*. Few, if any, contemporary societies closely resemble the republican ideal. The call for the common good thus should not necessarily be conflated with a call for the moral priority of population interests over individual allegedly narrow ones – as it is apparent in the quotation above by Bayer and Fairchild. The latter, indeed, may run counter the republican ethos if it becomes a domination of the common good equated with population health over the individual. The common good, in other words, is only realized when effective civic membership is granted to all morally relevant interests of citizens *qua* members of the polity. This means that particular attention should be paid to conditions of domination and systematic disadvantage that exist in society and make sure that all voices and needs have surfaced in the deliberation and properly acknowledged. The latter could be interpreted as a plea for enhanced public participation in the definition, framing, and eventually the pursuit of the common good. Participation may come in many degrees, from the establishment of deliberative public forums or through the consultation of the so-called 'public opinion', what is important in the context of republicanism, however, is not participation as such. It is important, instead, that all morally relevant interests inform deliberation, and that none of them is left out from the public purview because those who hold

them are a minority or, I would add, live in conditions of disadvantage that does not allow their voices to be heard or their interests to emerge. If we leave the language of political philosophy and come back to applied ethics, this means that the role of public health ethics is to specify the sources of normative concern in specific policies, and identify what are the places and spaces – both conceptual and physical - in which the exercise of public engagement is mostly due. In this vein, we can add another condition for the justification of public health interventions: inclusion in the decision-making process of the moral interests of all the parties that may be affected by an intervention.

To be sure, the necessity of including affected parties in the context of decision is not exclusively coming from the republican tradition. Indeed, also authors that do not explicitly subscribe to republicanism as a political philosophy underscore the necessity of public involvement in the deliberative process as to ensure the accountability of a public health decision. For instance, Childress et al. (2002, 172), note that: "When public health agents believe that one of their actions, practices or policies infringes one or more general moral considerations, they also have the responsibility, in our judgment, to explain and justify the infringement, whenever possible, to the relevant parties." What they claim, basically, is that ethical principles alone cannot eliminate the fact that individual interests may sometimes collide with collective needs. A process of public justification, though, makes sure that such trade-offs are made openly and with recognition of all interests. Similarly, Nancy Kass (2002) recognizes that, within a pluralistic society, how benefits and burdens are balanced, would lead to disagreement. This fact requires, in her view, the establishment of procedures, such as public hearings, so that minority views are taken into

account. The difference with the republican model, however, exists if not in the practical outcomes at least in the general substantive motivation requiring public justification. In the republican tradition, indeed, the call for a broader inclusion should not be motivated solely by the need to justify liberty infringement when it occurs, but also to show that the infringement required is of a non-dominating kind. That is, that the policy under consideration correctly tracks common shared interests and not only the aggregative outcomes of the interests that some groups have in common.

4. Conclusions

From the analysis of the beneficence-based model of public health, and the exploration of the central tenets of republicanism in political philosophy I draw two conclusions important for the present work and the following analysis. The first alerts us that the pursuit of population health can, at least sometimes, bring about conflicts with individual interests. Recognizing both as important the beneficence model seeks to establish some limiting conditions for the implementation of public health policies that also respect individual liberties. Among them the most important – at least for my purposes – are the harm principle and the 'least restrictive means' limiting condition. The second makes us aware that the concept of freedom is indeed broader, and urges us to think of it in terms of absence of arbitrary interference, rather than interference as such. In my interpretation, the republican tradition does not tell us that there are some predetermined substantive goods - i.e. population health as common good - that should take priority over individual narrow interests. It rather suggests that a policy is for the common good when it responds better than alternatives to shared common interests. In other words, the justificatory space

of public health activities cannot be limited to interests of non-interference versus population health interests only, but it requires an exploration of all the morally relevant interests that may be affected by a policy. The latter, I submit, can sometimes arise from engagement with the public. Insisting on the needs for major public engagement in the identification of public health goals, I claim, is a plausible condition for vindicating public health activities, escaping unjustified paternalism, and for paying due respect to individual preferences and population needs.

There is a sense in which broader spaces of participation in decisions affecting the public as a whole are worthwhile, one should not, however, commit the mistake of thinking that participation is all that matters. In many situations, participation is not possible for some individuals and groups in that they live in conditions of social disadvantage so profound that the, still valuable, opportunity of joining in a public forum for the deliberation of, for instance, the best way to implement a vaccination programme would rank at the bottom end of their personal priorities. In other words, social disadvantage can be seen itself as a form of domination and, its redress, may acquire moral priority. In this sense, the republican appeal to enhancing rights of civic membership, as opposed to the right of freedom from interference alone, needs to be accompanied with equally important issues explaining why it is important for society to protect health and see whether conditions of disadvantage map onto health outcomes.

In conclusion, the beneficence model address the question of how to balance individual and public interests, the republican approach emphasizes the notions of freedom as non-domination and common good as particularly fit to public

health. Both of them, however, do not sufficiently problematize why health is of specific moral importance. This is so either because the latter is taken as uncontroversial, or because it is subsumed - in some quick interpretations of the republican thought (see Bayer and Fairchild above for one example) - under the grand notion of population health. It is to the analysis of this point that I now turn.

Chapter two: Justice in public health. Fair equality of opportunity, capabilities and the negative aim of justice

1. Introduction

The two approaches presented in the previous chapter illustrate two different threads in the political and ethical interpretation of public health activities. Both accounts, despite the differences, recognize the moral importance of public health interventions and provide the theoretical background for their ethical evaluation. The debate rests, more or less explicitly, on the intuition that health is valuable and worth pursuing. Health has a special role for individuals, a role that goes beyond the enjoyment of a status of good bodily and mental functioning. Being healthy is a pre-requisite for much of the creativity, joy, and richness a person can obtain from life, or at least it makes it much more likely that one will be able to pursue the kinds of things one wants to pursue or the kinds of things one considers worth pursuing, according to one's conception of the good. Meeting health needs is, moreover, fundamental to sustain equal opportunity in the access to important roles and offices in society. A life free from disease and morbidity is an element that facilitates full participation in the polity, and it is thus important for the functioning of present democratic societies. Public health interventions, when properly implemented, sustain population health thus enhancing community life and, possibly, social cohesion. Therefore, there is at least a prima facie reason for considering public health activities as rightly tracking on important aspects of what is valuable in people's lives. Accordingly, the two different

approaches recognize some sort of obligation on the part of the governments to protect the health of their citizens and to restore such health when it is lost. The way protection is (or should be) instantiated in practice varies, as I have shown, according to their different philosophical and political persuasions.

In this chapter, I wish to enlarge my critical overview to issues of justice and see the ways in which those issues can be approached in public health ethics. This presentation is intended to provide further theoretical background for the analysis of the case study in the second part of the thesis, and to provide justification for the application of the relevant concepts that will appear in it.

Issues of distributive justice have certainly been acknowledged in medical and research ethics; the beneficence model in public health ethics makes no exception in this respect. The way the beneficence model frames the issue is, in my view, incomplete. The pitfall of this approach consists, primarily, in a thin view of the good public health institutions are distributing and the moral relevance of the social context in which distribution takes place. The analysis of the social context of distribution is important in that recent epidemiological findings are progressively increasing our understanding of the connections existing between socioeconomic and health status. In a nutshell, social epidemiology tells us that much of the health inequalities that we observe, to different extents, in various societies strongly correlate with inequalities in, among other things, income ad literacy. This realization may result in an enlargement of the scope of public health activities and, consequently, of ethical analysis beyond the classical concerns about the fair distribution of medical resources that typically occupy ethical debates in public health.

To elaborate on this point, and show its connections with the rest of the work, I will first specify the scope of my approach by showing how I intend to deal with the increasing recognition of health inequalities among different socioeconomic groups. In particular, I will explain that while my approach has a narrow scope in the object - since it is oriented to the ethical analysis of specific policies rather than on health policy in general – it is attentive to broader problems of health inequalities and their social determinants. I will argue that although we cannot expect public health to foster social justice in general, we can still reasonably require a negative aim of social justice for public health. In this respect, public health policies should be devised as to avoid worsening existing health inequalities. As it will become apparent in the final part of this chapter and of this thesis, one way to attend existing inequalities comes also from enlarging our evaluative moral focus from the medical resources people are provided with to their capability to transform those resources in actual valuable outcomes. In this respect, the introduction of the so-called capability approach will provide a further methodological tool to evaluate issues of justice in this work.

2. Justice and public health: narrow or broad?

Issues of justice have always occupied centre stage in bioethical analysis. In the now classic principlist approach, justice figures as one of the four principles that should inform an ethical approach to healthcare (Beauchamp and Childress 2009, 240-281). In the context of healthcare ethics problems of justice arise in, at least, two forms. The first is a narrow one, and pertains to the just allocation of medical treatments in the context of scarce resources (Winslow 1982; Veatch 2000; Ubel 2001; Truog et al. 2006; Hurst and Danis

2007; Persad, Wertheimer, and Emanuel 2009). Textbook examples of this perspective are questions of rationing within the health budget – i.e. what principles should guide the allocation of resources to different treatments – and issues of rationing of scarce treatments to different patients who need them – i.e. what are the right criteria to establish priorities (Beauchamp and Childress 2009, 267–281). The second is broader, and attempts to integrate health and healthcare provision and the traditional concerns of the theories of social justice in political philosophy. These latter problems arose especially in the United States, where there is no legal right to health care. Central focus of this account is to understand what is the special moral importance of health and whether it is an obligation of justice on the part of the state to offer equal access to healthcare or, ultimately, to a decent minimum of health to all its citizens (Buchanan 1984; Daniels 1985; Anand, Peter, and Sen 2006; Daniels 2008). Issues of justice also occur when we change the focus from healthcare delivery to public health activities. Several ethical frameworks in the beneficence model, for instance, incorporate concerns for justice as a part of public health ethical analysis (Verweij 2000; Kass 2001; Childress et al. 2002). As Nancy Kass (2004) notes, already in the 1980s - a decade in which the discussion about the necessity of improving access to healthcare in the United States was a hotly contested issue - scholars in bioethics agreed that some typical public health activities (like immunization) where the least controversial services to be included in a basic, minimum package of health services.

Also in the context of public health activities concerns for justice can be analysed either from a narrow or a broader perspective. In the first case, the main issue to be assessed would be whether the benefits and burdens of a given

public health interventions are fairly distributed across society. The beneficence model, presented in the previous chapter, generally endorses a narrow strategy. It understands ethical analysis in this field as an attempt to accommodate the conflicts that may arise among the general moral considerations informing public health activities. A problematic trade-off the beneficence model would recognise as ethically salient would arise when the most effective way of intervening against a public health problem does not reflect a fair distribution of the benefits and burdens of the intervention. A typical example of this problem is constituted by seasonal influenza immunization policies in Japan (Reichert et al. 2001; R. Faden and Shebaya 2010). Seasonal flu is, in general, a relatively mild and transient disease. This means that most of the times, otherwise healthy, individuals are able to pass through its symptoms without relevant complications. In some cases, however, influenza can have serious, also lethal, effects on a number of people: most notably, immunocompromised individuals and the elderly. Those people, because of their bodily vulnerability, are also more likely to develop adverse events after immunization. From a public health perspective, immunizing a critical mass of people, and thus trying to stop the epidemics, better controls seasonal flu than targeting high-risk groups directly. The Japanese policy follows this reasoning and thus targets kids in primary schools - a public space where epidemics of this kind are more likely to start spreading – to the major benefit of vulnerable people who may suffer the most from contracting flu. The question of fairness that would arise in the beneficence model would thus be the following: 'Is it right to distribute differentially the benefits and burdens of a given intervention?'. It is important to notice that the goods provided by policies like the Japanese are still providing a public good as defined in the

previous chapter. Everyone, indeed, is benefiting from the intervention. Not everyone, however, is benefited or burdened to the same extent. How to establish whether the proposed intervention is nonetheless ethical? The beneficence model is supposed to provide guidance for an answer to the dilemma along the limiting conditions previously outlined. In particular, the role of applied ethics would be to assess, given the specific details of the case at hand, whether or not the trade-off is acceptable. This activity, clearly, requires gathering a lot of specific information about risk and benefits of the intervention, its effectiveness, necessity and, as also indicated in the previous chapter, whether alternative, less burdensome, interventions would reach the same objectives.

In a broader sense, instead, the justice of public health activities can be adjudicated with reference to the ever-increasing recognition of the existence of health inequalities between and within countries. In the latter sense, the distribution of public health interventions is considered as only one of the societal factors determining health. A vast amount of evidence in social epidemiology is showing how the various health inequalities that we encounter both at the local and global scale do not depend solely on biological differences among groups of individuals, nor are they explained by reference to access to healthcare alone. Rather, a whole set of health indicators, like health status, levels of morbidity, and life expectancy vary, quite consistently, across different socioeconomic strata. Socioeconomic status (SES) hence is increasingly understood as an indicator of health status as well, and many researchers in social epidemiology are showing how it is not unreasonable to talk about social determinants of health. The literature on the social determinants of health

alerts us with at least four general findings (Daniels and Sabin 1997; Marmot 2004; Marmot 2005; Marmot, Wilkinson, and Brunner 2006; Daniels 2008). First, people belonging to the upper end of the socioeconomic ladder tend to have better health, in terms of life expectancy and premature death, than those belonging to the lower end of the spectrum. Second, the steeper the SES inequalities in a given society the steeper are also health inequalities. Third, these inequalities do not seem to depend on the level of access to healthcare services. This means that also in countries where universal access to healthcare is guaranteed, differences in socioeconomic status map onto differences in health outcomes. Fourth, the income/health gradient does not only affect people belonging to disadvantaged groups, but it operates along the whole socioeconomic spectrum. This means that in societies with high level of socioeconomic disparities, also people belonging to the less disadvantaged strata of society tend to have worse health than groups similarly situated in different societies with less inequalities[6]. The literature about the social determinants of health, moreover, is increasingly taken to be one of the bases for state action in the reduction of health inequalities within countries. One notable example of the growing importance of this approach is the review commissioned by the United Kingdom Secretary of State for Health to Marmot as to inform the government about the most effective evidence-based strategies for reducing health inequalities in England from 2010 (Marmot 2010).

[6] The epidemiological literature about the social determinants of health is vast. Although it has always been known that individuals' chance of life and death are patterned with social class, it is only in the last decades that this recognition is corroborated by evidence. The seminal study in this field is Michael Marmot's Whitehall Study I and II (1978; 1991), where it is shown that among British civil servants mortality was higher among those in the lower grade when compared to the higher grade. Ever since that study more evidence has been gathered. The references in the main text provide an overview of the most up-to-date findings in the field.

The social determinants of health have caused major debates within public health and bioethics as to how they should reconfigure common intuitions about the justice of health care systems and, consequently, fair distribution of health resources (Evans 2001; Kamm 2001; Peter et al. 2001; Ruger 2004; Rogers 2007). In fact, if health outcomes are determined only to a certain extent to the way the healthcare systems work then major concerns about health should be concerned not so much on issues about the distribution of given medical interventions, but on broader social and political aspects that are themselves highly contentious. As a supporter of the beneficence model would notice (see for instance: Anomaly 2011), the importance of the social determinants of health is, on its own, not decisive as to whether we should count health inequalities unjust nor, by itself, it tells us how to change our theories of social justice accordingly. Nevertheless, it suggests that if we grant health and health equity special moral importance, then a narrow focus on the distribution of healthcare alone is insufficient. As Norman Daniels notes, few people, except perhaps radical egalitarians, oppose all forms of socioeconomic inequalities. Many people, however, are much more puzzled when come to know that socioeconomic inequalities that otherwise seem just are then conducive to health inequalities (2008, 81). A broad analysis of the demands of justice with regards to health policies, hence, would also come into terms with the issue of health inequalities and assess when they are also unjust.

3. Justice in public health: a comparative or a transcendental framework?

In the previous sections I have proposed a distinction between narrow and broad approaches to issues of justice in public health. The first are

concerned primarily with problems of distribution as they arise in specific settings. In this sense, the social arrangement in which distribution takes place does not occupy central stage into the ethical analysis. The second approach, instead, takes problems of justice upstream, and considers the distribution of health services as having limited, though important, impact on the health of individuals and groups. There is a second distinction that can be drawn, moreover, as to how to approach problems of justice in public health. One approach is, institutions oriented or, following Sen's (2009) terminology, arrangement-focused. It seeks to analyse problems of justice by devising what would be the principles guiding a perfectly just society. In this respect, again in Sen's terminology, it can be labelled transcendental institutionalism. For the purposes of this work, I will take Rawlsian theories of justice as applied to health policy as representative of this approach.

The second approach, instead, is more interested in creating a conceptual and linguistic space for assessing individual well-being. In this respect, while the former approach was arrangement or institution-focused, the approaches of the second kind are realization-focused and look at what socially situated individuals fare with respect with existing conditions rather than only on what are the principles that should inform just institutions. The account I will take into account as representative of this orientation is the capability approach by Sen (1980, 1999, 2009; Sen and Nussbaum 1993).

A word of caution is, however, due. It would be wrong, indeed, to push too far the divisive issues in place between a Rawlsian theory and the capability approach. The two, in fact, respond to different demands, and one does not exclude the other (Daniels 2008, 64–71; Nussbaum 2006, 54–69). To the purposes of conceptual disambiguation, however, it is worth dedicating more

space to the analysis of the differences. The following exposition would also serve to justify when I will use, in the analysis of the case study, the language and conceptual tools of the capability approach and when those of the Rawlsian framework.

In the following sections, hence, I elaborate on the notion of health, and its value. In particular, I ask whether health can be conceived of as a proper object of distribution according to principles of justice. The questions that inform this section can be framed as: is there a duty, beyond beneficence, on the part of the state to meet, at least basic, health needs? Is this an obligation of social justice?

3.1 The transcendental route

The most influential among the approaches of the first kind are those inspired by *A Theory of Justice* by John Rawls (1971), and recently extended to the domain of healthcare and public health by Norman Daniels (1985; 2008)[7]. If, in a Rawlsian vein, we believe that a just society should leave open access to offices and incomes to the talents and skills of individuals, rather than to inherited structure of familial relations, then rational individuals should agree that the state also has the power to redistribute some important goods. More specifically, in *A Theory of Justice*, Rawls argues that justice demands the fair

[7] Rawls' work is a milestone in political and moral philosophy, but it has not gone without critiques (for browsing the vast literature on Rawls see, among others: Wellbank, Snook, and Mason 1982; DiQuattro 1983; Sandel 1984; Gutmann 1985; Kukathas and Pettit 1990; Norman 2011 and references therein). Rawls, in response to the huge debate following his work, has further specified his theory in *Political Liberalism* (1993). Critical analyses of *Political Liberalism*, which can also serve as general references, are the works of Habermas, O'Neill, and Nussbaum (1995; 1997; 2011). Since this work is mainly concerned with issues of justice as they arise in the context of healthcare and public health, I will use Norman Daniels work (1983; 2008) as representative of a Rawlsian approach to health.

distribution of primary goods (basic rights and liberties, freedom of movement, free choice among a wide range of occupations, offices and positions of responsibility, income, wealth, and the social basis of self respect) defined as those "things it is rational to want whatever else one wants. Thus wanting them is part of being rational" (Rawls 1971, 223).

According to Rawls, rational people behind a 'veil of ignorance' – that is people who are in what he calls the 'original position' and do not know anything about their natural endowments and social circumstances - would choose principles that would distribute fairly the primary goods. In contrast to welfarist theories that reduce well-being to experiential states like preference satisfaction, the list of primary goods provided above indicates who is better off and who is worse off from the perspective of justice. In particular, people behind the veil of ignorance would choose two principles of justice. According to the first principle: "each person is to have an equal right to the most extensive liberty compatible with a similar liberty for others." (Rawls 1971, 60) The second principle, instead, has to do with social and economic inequalities. In Rawls' theory the latter are permitted when: a) they are to the greatest advantage of the worse off member of society (also called the difference principle), and b) offices and positions are open to all under conditions of fair equality of opportunity (1971, 302–303). The principles of justice are supposed to apply to the basic structure of society; moreover, whatever arrangement distribution follows from the application of these principles is fair or just according to Rawls.

As Daniels suggests (2008, 50-51) Rawlsian fair equality of opportunity is supposed to be an improvement on the liberal political ideal of formal

equality of opportunity; that is, the idea that offices and positions of responsibility should be open to talent and natural skills. In several societies a long history of race and gender discrimination, however, has led to an underdevelopment of these expectations that continues also after discrimination becomes illegal. The actual achievement of jobs and offices, then, can be subjected to the strong effects of morally arbitrary social contingencies. The resulting inequalities, moreover, can perpetuate through the channels of existing family and social structures, thus leading to unequal development of talents and skills. Rawls' fair equality of opportunity, hence, would serve to mitigate the morally arbitrary effects that the social lottery may have on the development of natural skills and talents. As Daniels notes (2008, 52-53), public education is extremely relevant from the perspective of the conception of justice as fairness in that it would partly correct for the moral arbitrariness of social contingencies. Another morally arbitrary lottery, in addition to social circumstances, is the natural lottery in the distribution of talents and skills. In Rawls view if we are, on the one hand, in part responsible for the way we develop our skills, we are not, on the other, in control of what talents we are born with. The combined action of the natural and social lottery thus makes classical appeal to formal equality of opportunity insufficient. It is in this sense that the difference principle further mitigates their effects by requiring that the basic structure of society works to the advantage of all. As Rawls notes (1971, 100-104), no one deserves his starting place in society, or his natural endowment. Nevertheless, justice does not require the elimination of these distinctions. As he writes:

> The natural distribution is neither just nor unjust; nor is it unjust that persons are born into society at some particular position. These are simply natural facts. What

is just and unjust is the way that institutions deal with these facts. Aristocratic and caste societies are unjust because they make these contingencies the ascriptive basis for belonging to more or less enclosed and privileged social classes. The basic structure of these societies incorporates the arbitrariness found in nature. [In justice as fairness instead] men agree to share one another's fate. In designing institutions they undertake to avail themselves of the accidents of nature and social circumstance only when doing so is for the common benefit. The two principles are a fair way of meeting the arbitrariness of fortune; and while no doubt imperfect in other ways, the institutions which satisfy these principles are just. (1971, 102)

In Rawls original theory meeting health needs was not taken into account as one of the major issues of justice. In the original position, indeed, the contractors are assumed to be fully functional individuals. Although Rawls himself has partially redressed this unbalance in his later works (2001, 173–175), the most elaborated inclusion of health issues into a Rawlsian theory of justice is due to Norman Daniels. In Daniels' system, meeting health needs is important for justice in that it serves fair equality of opportunity. Clearly, one of the major problems Daniels' account has to meet pertains to the definition of what counts as a legitimate health need. Daniels derives the biostatistical conception of health from Boorse (1975; 1977;1997), and argues that legitimate health claims, are claims to normal species functioning, and health is, derivatively, absence of disease (2008, 36-42). The conception of health as normal species functioning is contested in the specific literature[8]. It is however

[8] The notion of health Daniels decides to adopt as a starting point for his analysis of the connections between health and justice does not go without critiques in the philosophy of medicine literature (Reznek 1987; Wakefield 1992; Amundson 2000). For instance, Boorse's naturalistic account has been attacked by those who attach normativity to the notion of disease. In the latter accounts 'health' and 'disease' depend, for most part, on valued judgments: disease is hence an unwanted condition. What counts as a disease,

acceptable, according to Daniels, as a reference for a theory of justice, in that it is publicly checkable through the methods of biomedical sciences and provides, at least, clear cut cases of what counts as normal and pathological. Meeting health needs so defined, hence, is important to provide to everyone a normal range of opportunities as they are present in that society. The normal range of opportunity represents the range of life plans a person may reasonably want to pursue given her talents and skills.

Health, hence, is not only important on its own, but also because it is instrumental for assuring to individuals a normal opportunity range within society. Disease and disability, in this context, are seen as barriers that severely limit the range of opportunities that are available to us. In his recent works, moreover, Daniels includes concerns for the social determinants of health and argues that health inequalities are also inequities when follow from unjust social circumstances. In his elaborated revision of Rawls theory (Daniels 2008, chapter 3), Daniels argues that health inequalities are not always unjust, but only when the determinants of health are not distributed according to Rawls' (and hence his own as applied to health and healthcare) principles of justice. In more practical terms, Daniels' approach calls, as a requirement of justice, for policy actions in all those areas that can have an impact in those fields. In particular he cites: investments in early childhood development, nutrition programmes, public health, primary healthcare, measures to protect income, and improvements in the quality of the work environment (2008, 95-97). Preventive measures, moreover, are specifically required by a theory of social justice. As he claims, when the risk of getting ill falls unequally on different

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furthermore, depends on spcific historical and cultural circumstances (Margolis 1976; Engelhardt 1986). For a recent critical analysis on the debate about the definition of health see (Ereshefsky 2009).

groups, and do so systematically in a way that is avoidable, specific policy action is required as to avoid also differentials in equality of opportunities. As one commentator notes, the force of Daniels' arguments is to show that social inequalities "are unacceptable to the extent that they produce health impairments that impede people's capacity to pursue the life plans that it would be reasonable for them to pursue if they were not so impaired" (Buchanan 2008, 19).

This point, however, needs clarification. What matters is not to achieve equality as such. After all, equality in health status may be reached also through a levelling down move. In other terms, we could equalize risk to get ill equally across the whole social spectrum by worsening the prospective health status of the better-off. Clearly this move would be unsatisfactory. For related reasons, some inequalities may not be unjust either because they are unavoidable – i.e. think for instance at differences in life expectancy between women and men that seem to be due to biological differences – or because they are necessary. As to this last issue, suppose that there exists a difference in life expectancy among truck drivers and clerks due to the different environments in which they work, and the former having on average decreased life expectancy. We would probably be concerned by this inequality and put in place a series of interventions so to make truck driving as safe as possible. Suppose further that there remains a high mortality rate that, given the importance of trucking, seems unavoidable or necessary (Daniels 2008, 90). In this case, we would perhaps moved to think that the inequality does not also constitute an inequity. The discussion about whether health inequalities are also unjust may continue. In particular, it may be raised the point as to whether those inequalities that

would persist after a fair distribution in Rawlsian terms - the so-called residual inequalities - would be unjust. As shown by Rawls' quotation above, they will be perhaps unfortunate but they will be not be the result of an unjust social arrangement and thus morally permissible. Nonetheless, as the example of the truck drivers suggests, a just society has the duty to put in place measures that are for the protection of all. More precisely, the Rawlsian theory calls for public health policies that equalize risk in that they are functional to provide fair equality of opportunity to all. As Daniels claims: "Public health services promote the conditions that reduce certain risks of disease or disability. They reduce risk by assuring clean, safe living and working environments and by protecting against infectious diseases. These services should attend to the risks faced by the entire population and aim to reduce these risks in an equitable fashion" (Daniels 2008, 143). Moreover, the difference principle indicated above – that is, inequalities are permitted insofar as they are to the greatest advantage of the worse off - should not be intended, Daniels suggests, as a sheer trickle-down principle requiring only that the poorest gradually benefit as a result of the increasing wealth of the richest, rather as implying maximal flow to the worst-off groups (*ibid.* 93).

In this section I have illustrated that public health interventions find a justification in justice in that they serve to foster fair equality of opportunity. I have moreover indicated how justice, at least in the view presented, requires maximal flow towards the disadvantaged strata of society. Clearly, the approach here presented only provides the theoretical basis to understand how the basic structures of society should be organized to be just. It tells us that public health is one of those activities that a just society supports. Nevertheless, the approach

does not tell much how to assess whether a given policy is just in specific circumstances. In virtually all cases, public health policy is done in contexts in which already exist health inequalities and some of them would perhaps persist also after policy action. It is thus important also to specify what justice requires in specific policy contexts. In this sense, the transcendental route does not offer much guidance.

3.2 The comparative route

Institutionally-focused approaches do not tell us how different public policies fare with respect to one another, or can ameliorate social circumstances in real world settings. Rather, they provide the transcendental conditions of an ideally just society. In contrast, the comparative approach takes into account human diversity and individuals' socially situated circumstances. In this approach, what people can do and be with the resources they are provided with is another important focus for approaching the demands of justice. This account arises from key insights by Nobel-Prize winning economist and political philosopher Amartya Sen (1980), and has been progressively refined, among others, by Sen himself and Martha Nussbaum (Nussbaum 1992; Nussbaum and Sen 1993; Sen 1993; Sen 1995; Sen 1999; Nussbaum 2006). Initially conceived as an approach for the analysis of human development and global inequalities, the capability approach (as it is generally labelled) has been extended as fit also to the analysis of public health in affluent countries (among others see: Powers and Faden 2006; Ruger 2010). The core distinction in in the capability approach is the one between the means and the ends of well-being. Only the latter are intrinsically valuable, whereas means are only instrumental to reach the goal of expanding well-being. According to the capability approach, well-being should be discussed in terms of people's capabilities to function, that is, on their

effective opportunities to undertake the actions and activities that they have reasons to engage in. These beings and doings, called achieved functionings, together constitute what gives value to life. Functionings include working, resting, being literate, being healthy, being part of a community, being respected, and so forth[9]. The distinction between achieved functionings and capabilities is between the realised and the effectively possible, in other words, between achievements and freedoms. What is ultimately important is that people have the capabilities (freedoms) to lead the kind of lives they want to lead, to do what they want to do and be the person they want to be. Once they effectively have these capabilities, they can choose to act on them in line with their own ideas of the kind of life they want to live. Whereas Rawlsian theories of justice provide us with distributive principles that are supposed to define a just social structure, and in this respect they can be said to be ideal theories, the

[9] Whether the capability approach requires a definite list of sets of capabilities and functionings is controversial (Robeyns 2005). Nussbaum (2006, 76–78) provides us with a list of what she calls 'central human capabilities' and are: 1. *Life*. Being able to live the end of a human life of normal length. 2. *Bodily Health.* being able to have good health, including reproductive health; to be adequately nourished; to have adequate shelter. 3. *Bodily Integrity*. Being able to be secure against violent assault, including sexual assault. 4. *Senses, Imagination and Thought*. Being able to use the senses, to imagine, think and reason. Being able to use one's mind in ways protected by guarantees of freedom of expression with respect to both political and artistic speech, and freedom of religious exercise. 5. *Emotions*. Being able to have attachments to things and people outside ourselves. 6. *Practical Reason*. Being able to form a conception of the good and to engage in critical reflection about the planning of one's life. 7. *Affiliation.* Being able to live with and towards others, to engage in various forms of social interactions. 8. *Other Species*. Being able to live with concern for and in relation to animals plants and the world of nature. 9. *Play.* Being able to laugh, to play, to enjoy recreational activities. 10. *Control over One's Environment*. Being able to participate effectively in political choices that govern one's life; having the right of political participation. Similarly, Powers and Faden (2006, 16–29) provide a list of six capabilities or, as they call them, essential elements of well-being, that are: Health, Personal Security, Reasoning, Respect, Attachment, Self-determination. For the purposes of this work I am not providing, nor subscribing to, any of these lists. I am interested solely on the difference between functionings and capabilities and why a focus on the latter can enrich moral analysis more than an insistence on functionings or achieved outcomes alone. For a discussion as to whether the listed capabilities are essential human entitlements and whether they hold irrespectively of cross-cultural variations see: (Nussbaum 1997; Sen 2004; Sen 2005).

second approach is intended to offer guidance in practical world problems and, in particular, on what inequalities matter most when ideal just institutions are not in place. In this respect, approaches of the second kind can be called non-ideal theories. In the words of Powers and Faden:

> [Non-ideal theories] view facts about inequality as essential context information, necessary to the task of understanding when inequalities of any sort merit heightened moral scrutiny. Real but socially contingent inequalities such as poverty, inequalities in power and social standing, and ethnic and gender discrimination therefore matter for our very different theoretical task. From the perspective of non-ideal theory, only when such facts about concrete human condition figure into the analysis is the task of saying which inequalities matter most comprehensible. (2006, 31)

The capability approach thus departs from those theories of justice like Rawls', which seek the transcendental conditions for the construction of a just society, and judge the justice of actual societies according to their distance from the theoretically developed idea. On the contrary, the capability approach is realization-focused rather than arrangement-focused (A. Sen 2009, 5–19). The capability approach, moreover, should not be intended as a grand metrics telling us how a society should be organized and inequalities redressed, but rather as a focal variable for the assessment of individuals' disparities with regards to the capabilities they possess. In this account more importance has to be attached on questions like 'how justice would be advanced in this particular situation?', rather than on issues like 'what would be perfectly just institutions?'. In this vein, the capability approach takes a comparative route and focuses on actual realizations in the societies involved, and the actual lives people can effectively lead. In this respect Sen claims:

The importance of human lives, experiences and realizations cannot be supplanted by information about institutions that exist and the rules that operate. Institutions and rules are, of course, very important in influencing what happens, and they are part and parcel of the actual world as well, but the realized actuality goes well beyond the organizational picture, and includes the lives that people manage – or do not manage – to live. (A. Sen 2009, 9)

In this sense, the capability approach is a ductile tool for the evaluation of public health performances, and in this way I will use it. The specific questions of justice that I will ask will thus change slightly, but I argue importantly, from those usually pursued within the beneficence model. The capability approach, hence, should not be understood as a comprehensive theory of social justice, but rather as a tool for: a) assessing individual well-being; and b) the comparison of social arrangements and social policies. The particular advantage of such an account stems from its being inspirational rather than strictly prescriptive. As Sen (2009, 232) has recently noted: "The capability approach points to an *informational focus* in judging and comparing overall individual advantages, and does not, on its own, propose any specific formula about how that information may be used. Indeed, different uses may emerge depending on the nature of the questions that are being addressed". In the course of the last chapter of this work, I will use this tool to enlarge the scope of previously made analysis.

3.3 Public health, capabilities and well-being.

What matters for the purpose of this work is that, once the capability language enters the stage of ethical analysis, problems of distributive justice can be framed in a more comprehensive way than the beneficence model permits. Indeed, in the latter a standard problem of distributive justice would amount to

the fair distribution of public health resources irrespective of morally neutral categories like income, race ethnicity, or sexual preferences. When supplemented with the tools of the Rawlsian approach, moreover, the beneficence model can also provide criteria for just distribution (i.e. the difference principle) of medical resources. The capability approach easily accommodates those concerns, but licences more than that. Remarkably, it is also able to indicate how differently situated individuals can actually convert resources into functionings (medical resources into health functionings in the case of this work) they have reason to value. If the focal variable for public health policy evaluation is, as I maintain it should be, capabilities to health rather than distribution of public health goods only, then we are well positioned for a more fine-grained ethical analysis also along the lines developed in the previous sections. In other words, adopting the perspective, and the language, of the capability approach allows us to understand differently what are the reciprocal obligations among the entities of the triad (state, individuals, communities) discussed above. Accordingly, the government's duty towards citizens does not consist in reducing, and preventing harm as such (although sometimes, depending on the severity of the situation at hand, this may be the thing the government has to do), but rather to provide enabling conditions for citizens, in their different economic and social circumstances, to achieve valuable health functionings if they so wish. In other words, the capability approach enlarges the scope of how freedom should be understood – i.e. freedom to achieve valuable functionings and individual well being versus mere freedom from interference – and, consequently, of what social justice implies – i.e. ensuring that individuals can achieve effective freedom so defined.

Clearly, the adoption of the capability perspective does not, by itself, dissolve all the ethical problems as they arise from the beneficence model. In some contexts the clash between individual liberties and population outcomes will be inevitable as, for instance, in the case of dangerous epidemic outbreaks. In those contexts, hence, ethically problematic decisions have to be taken as to which of the two has to be privileged. Accordingly, the limiting conditions of public health activities as devised by the beneficence model would, by and large, be the right tools for deciding appropriately in those circumstances. The capability approach therefore has not to be seen as completely replacing all other kinds of ethical analysis, nor it necessarily pushes to the background all the ethically problematic issues as they arise from the latter. Quite on the contrary, the capability approach serves to enlarge the scope of ethically sensitive issues in public health and to supplement them with a further layer of analysis.

Extending the focal variable of policy evaluation from the distribution of health resources to health capabilities, moreover, allows us to assess public health interventions also against the broader effects they may have on dimensions of human well-being other than health. An example drawn from Faden and Powers (2006, 17) is illuminating in this respect. They observe how policies against female genital mutilations certainly rest on concerns for health. These policies, however, have also impacts on considerations for the physical and psychological inviolability comprised by the dimensions of personal security and self-determination. In this case the moral foundation in justice for these interventions does not rest solely on one dimension of well-being, namely health. It rather draws upon three dimensions, each of which being a genuine

source for moral concern. The moral foundation of public health policies does not depend solely on how medical services are distributed, or ethical evaluation need to be confined on how policies affect health as one dimension of well-being. It also depends, and thus would be the approach I will endorse in the analysis of the case study, on how the policy impacts on the other dimensions of well-being.

For these reasons mentioned, I would like to conclude this chapter by making explicit how I will evaluate the policies of my case study from the perspective of justice. The next two sections are hence dedicated to the analysis of these points.

4. Conclusion: the negative aim of justice

The issues above presented, especially the recognition of the role played by the social determinants of health, indicate how problematic it is to assess public health policies from the perspective of justice. More specifically it is important to clarify whether it is more appropriate to address these issues from a narrow or a broad perspective. If one follows the narrow perspective – the one adopted in the beneficence model – the advantage for ethical analysis would be in terms of its practical manageability. Given a public health initiative, for instance, the role of applied ethics would be to scrutinize whether the intervention is distributed so to include all the people who may need it irrespective of morally neutral categories like gender, ethnicity, and socioeconomic status. In the narrow perspective the only legitimate goal of public health is the provision of public goods as defined in the previous chapters.

If one adopts the broad perspective – along the lines suggested by Daniels and Sen - a whole new set of state interventions would open up to ethical analysis. The advantage for this kind of analysis would be in terms of breadth. Incorporating the problem of health inequalities, and their multifaceted determinants, would, at least in principle, allow the analyst to understand what are the socioeconomic circumstances that negatively affect health. Consequently, this realization would provide the space to call for intervention also on those contexts rather than on medical provision alone. What this kind of analysis would earn in breadth, however, it may lose in terms of focus. This loss may result both practically and conceptually problematic. It would be so practically, in that it would potentially transform every policy in a health policy and, consequently, every problem of justice in society in a problem of health justice. This conflation, if occurred, would probably obscure the reason why some injustices in certain contexts are so irrespective of the health outcomes they may give rise to. Perhaps more importantly, this can also result in an undue expansion of the goals of public health. As Gostin argues: 'Just because war, crime poverty, illiteracy, homelessness and human rights abuses interfere with the health of individuals and populations does not mean that eliminating these conditions is part of the mission of public health" (Gostin 2001, 72). The loss of focus proves conceptually problematic too. Some would maintain, along Walzerian lines, that this perspective is faulty in that different social goods (income, wealth, work, health) have different social meanings and so they are better divided up into different 'spheres of justice', each with its own distributive principles (Walzer 1983). In this view inequalities in different spheres are acceptable as long as there is not one sphere dominating over the others. In this respect, since the social determinants of health literature has

been able to show only correlations, and not causation, between socioeconomic status and health outcomes, it would be wrong to draw far reaching ethical and political consequences from it.

Both intuitions have their own merits. This work, however, does not try to adjudicate between them. This does not mean, however, that it floats between the two. This is so for the focus of the thesis. I am interested in the ethical analysis of a specific public health initiative – namely Human Papillomavirus vaccination programmes – and not in providing a complete theory of social justice, or a foundational of empirical work about the social determinants of health. My analysis is thus both narrow and broad. It is narrow in that I analyse the ethical implications of a set of policies as recently instantiated in several countries worldwide. In this sense, I am not concerned with establishing whether health inequalities are primarily socially determined or not. Although I think the literature cited has certainly shown evidence as to this correlation, I also agree, along the lines of the above quotation by Gostin, that the specific role of public health policy makers is not to devise policies in areas that go beyond their professional competences. This claim, however, need not to be confounded with another one, which seems to be implied by some supporters of the beneficence model. Anomaly (2011), for instance, argues that public health should only aim at the provision of health-related public goods. All other health-related issues such income, housing, and illiteracy, so the argument goes, pertain to 'tangentially related endeavours, such as social work, charity, and human rights campaigns' (ibid., 1). If this claim is understandable as to the goal that should inform professional practice for public health workers, it is certainly not extendable to public health ethicists. Indeed, if an

argument is provided as to the special moral importance of the health of individuals within particularly disadvantaged populations or social groups or, alternatively, if the idea of population health is taken to have specific moral significance, then attention to the fact that many health outcomes are socially determined becomes a legitimate source of morally relevant information also from the perspective of moral and political philosophy. In this vein, although it is acceptable to say that public health policies should be restricted to the provision of medical goods – and not advocate for broader redistribution of income - it is not likewise acceptable to conclude that moral and political analysis should be blind with regard to the multidimensional sources of health determinants and how they impact on what individuals can do and be with the goods they are formally provided with.

Despite disagreement as to how intervening on health inequalities - whether intervention on the social determinants themselves is desirable – a point of agreement could be found in the specification of, at least, a negative aim of justice for public health. The negative aim of justice requires that public health policy give special moral importance to those health inequalities that are attached to existing patterns of systematic disadvantage across several dimensions of well-being and individuals' different socioeconomic status. Powers and Faden argue (Powers and Faden 2006, 87-95) that health inequalities that overlap with other dimensions of disadvantage in different spheres are among the most invidious. Accordingly, public health policies should, at least, be devised as to prevent the worsening of the inequalities that present those connections. Of particular moral urgency, for instance, are those health inequalities that identify differences between socially dominant and

socially disadvantaged groups. They cite classical example of group domination in its various forms of race, gender or sexual orientation discrimination. These kinds of disadvantage often compound with one another, giving rise to clusters of disadvantage with negative effects on a variety of dimensions of well-being. For instance, it is not only true, as observed by the literature on the social determinants of health, that disadvantage in socioeconomic status correlates with disadvantage on health status. It is also true that a diminished capacity of avoiding premature mortality or invalidating morbidity may in turn have effects on the socioeconomic status, in terms of less opportunities to access jobs and offices that are relevant within a society. Moreover, disadvantage in terms of socioeconomic status can have effects on the extent of effective political participation of people so situated. Policies taking into account these aspects, then, would not only have beneficial effects on health, they also have a positive role in that they are public manifestation of respect of the needs of everyone, no matter their social position. Public policies that seriously take into account those issues are public manifestation of the value of each and every individual, and would have, besides favourable health outcomes, also positive effects in terms of enhanced public trust and social cohesion.

If we take the negative aim of justice as a matter of overlapping consensus among people holding different comprehensive views about what social justice would require in general terms, then how policies serve this scope becomes an important aspects under which public health policies can be ethically evaluated. Clearly public health policies can fulfil the negative aim of justice in different ways. For instance, by devising specific actions as to effectively reach all the strata of the population. For example, one can think at

community based interventions, like educational and promotional campaigns, in those areas where is most needed. A vast number of these policies currently exist, and they are certainly admirable. I would rather argue that a further way for understanding justice in public health policies requires also a prior understanding, and possibly a clarification, of what goods public health policies should distribute. I will provide an answer to this latter point in the course of the last chapter of this work, where I will show what the HPV policies should attempt to maximize and equally distribute capabilities to health rather than vaccines only.

5. Concluding remarks on thesis part 1

The critical analysis of the arguments presented in this chapter and the previous one serve as a tool for clarifying the theoretical means I will use in the analysis of the case study. Problems of distributive and social justice hence are not conceived, in this work, as solely dependent on institutional arrangements and how the latter are able to allocate medical goods proficiently. Nor, I have argued, the right focal variable for policy assessment can be functionings, or achieved outcomes, alone. The problem is certainly vast, and this work is not aimed at covering it in its full complexity. I will thus confine myself on the assessment of the merits of the various HPV vaccination policies and what are the criteria that may led us to prefer one over the others. In this evaluative exercise I make use of the ethically problematic issues highlighted in the previous sections. In this respect, how the different policies impact on people's liberties, whether the collective goods they are pursuing (public or common) are proportional with the goals they are supposed to achieve, and whether they provide sufficient space for the exercise of civic membership by the people

affected by the interventions, are all questions relevant for the purpose. Also relevant for my purposes, however, is to investigate whether the policies I will analyse are contributing to fulfil the negative aim of justice or, instead, if the way they are implemented may contribute to the worsening of existing inequalities. In assessing the performance of those initiatives in terms of justice I am not confined to the idea that justice is served by a fair distribution of the intervention itself (i.e. if it is formally available to all who need it). I would rather argue that looking upstream to overall health inequalities, and to those specific to the context, would prove useful for a better appreciation of the demands of justice. More precisely, I assess public health policy performance also from a broad perspective in which what counts as ethically relevant is not only what resources are formally provided to people, but also what people can do with that resources. For instance, whether they are able, given specific circumstances, to convert those resources that are formally available to them into valuable health outcomes. All these questions - and here is where issues about health inequalities become pertinent - become visible only when knowledge about the diverse social positions (and possible patterns of systematic disadvantage) different individuals find themselves into is taken into account. In this respect the introduction on the capability approach has provided the conceptual tools to assess how individuals' level of advantage and well-being can be understood.

Part 2: Case Study

Chapter three. Cervical Cancer prevention and its ethical dimensions. The Human Papillomavirus (HPV) vaccination case

1. Introduction

In the introduction to this work I have shown how the problem of cancer control depends on several factors that I have briefly illustrated in their complexity. I have shown how the quest for new cures and treatments is beset with promises and problems, and how preventive actions are currently recognized to be an appropriate complement for reducing the incidence of the disease. Moreover, I have indicated HPV vaccines among those biomedical innovations with a huge potential for cancer preventive practice. In the previous two chapters, moreover, I have provided the theoretical background and relative terminology that will prove useful for the remaining part of this work that will be dedicated to the close ethical scrutiny of HPV public health policies.

The present chapter is divided in two parts. In the first part I will provide a picture of the biological and medical features characterizing HPV infections, and how immunization can contribute at reducing the burden of cervical cancer and other HPV related morbidities. The first part of the present chapter therefore provides the necessary empirical background for the ethical analysis that would be developed along the lines of this work.

In the second part, instead, I will embed HPV vaccination into the broader context of vaccination and show how HPV reshapes some of the 'old' problems

that mass immunization campaigns have encountered. From the illustration of the public debate that has accompanied HPV introduction in several public health systems I will let emerge competing values or, as I call them, morally grounded interests that call for normative resolution. I will conclude the chapter by showing how some of them are of particular relevance for informing the analysis of the following chapters.

Before proceeding to the ethical analysis, however, we need more acquaintance with the biological and epidemiological features of the virus itself as well as with the disease burden it brings about. To this point I now turn.

Part 1. Immune from cervical cancer: the promises of HPV vaccination

2. The etiology of cervical cancer in historical perspective

In 2008 the Nobel Prize in Physiology or Medicine was awarded to Françoise Barré-Sinoussi and Luc Montagnier. Barré-Sinoussi and Montaigner's work was fundamental in the identification, in 1984, of a virus that undoubtedly resonates terrific to the general public: the human immunodeficiency virus (HIV). HIV and its link with AIDS hardly need introduction, nor will I dare reconstructing how its discovery mobilized the scientific community, public opinion, health activists, and public health practitioner in the 1980's (for such a description see, among others: Mann and Tarantola 1996; Epstein 1998). That day, however, HIV and its discoverers had to share the stage of the Karolinska Institute in Stockholm with another, less known, virus and another brilliant scientist. The Nobel Foundation, indeed, decided to award the prize also to Harald zur

Hausen, from the German Cancer Research Centre in Heidelberg (Germany), for having established the causal link between HPV and cervical cancer. As the statement explaining the reasons for the award says: "Dr. zur Hausen went against current dogma by postulating that the virus caused cervical cancer"[10].

The history of HPV is one of long, labour-staking scientific efforts followed - after much of its biology was elucidated, the sexual route of its transmission clarified, and its link to cervical cancer established - by a fuss of emotional responses at the political level after prophylactic means for its control were introduced in various public health systems. Before entering the complexities of the ethical and political dimension of HPV vaccination campaigns, however, a glimpse into the earlier understandings of cervical cancer causality is worth.

Although cervical cancer has been described since ancient times, the first systematic study of its causal roots is due to an Italian surgeon, Domenico Antonio Rigoni-Stern, who in 1842 published a study "Fatti stastistici relativi alle malattie cancerose"[11] where some interesting epidemiological notions of cervical cancer were described (Rigoni-Stern 1842). Rigoni-Stern was a provincial surgeon of the city of Padua and, in his review of the mortality records from the town of Verona between 1760 and 1839, noticed that higher deaths of this cancer occurred among old married women and relatively young prostitutes, while the disease was practically absent in nuns. As noticed by some scholars, at those times the idea of a sexually transmitted agent was still not elaborated. Etiologic theories were, instead, concentrating more on

[10] The info reported can be found at: http://www.nobelprize.org/nobel_prizes/medicine/laureates/2008/press.html (Last access: 16th November, 2011)

[11] The English translation of Rigoni-Stern's work reads: "Statistical facts about cancer", and can be found in: (Scotto and Bailar 1969).

moralizing notions about the women's body and their aberrant behaviours. Although cellular theories replaced such moralizing discourse by the end of the 19th century (see Nolte 2008; moreover, see Braun and Phoun 2010 for sociological implications of those theories), it was not until the 1970s that etiological theories became more specific. In those years several causative agent were postulated as initiators of cervical cancers. Among them were cited: infectious and non-infectious transmissible agents, such a syphilis, smegma from uncircumcised males, spermatozoa (Jeffcoate 1975), and later the herpes simplex type 2 virus (HSV2) (Frenkel et al. 1972; Kessler 1981). The connection between cervical cancer and a sexually transmitted virus was reported in an influential review by Rotkin (1973). He observed that: " the act of coitus effectively launched risk, and an agent of some kind was passed from male to female during this time of life when cervical epithelium was most readily available for transformation. There were and are a number of candidate agents. […] The speculation now is that one of these carcinogenic influences may be herpesvirus type 2" (*ibid.* 1354-55).

In 1976, however, zur Hausen published a short note in *Cancer Review* in which he challenged the received view and proposed a role for what he called the "condyloma agent" (zur Hausen 1976). Zur Hausen observed that genital warts, or condylomata acuminata in medical parlance, contained papillomaviruses and had the same epidemiological profile of several anogenital cancers, most notably cervical cancers. Given the high presence of genital warts in what he calls "populations of high sexual promiscuity" (*ibid.* 794), he suggested that the virus could be sexually transmitted and turn malignant in some occasions. We now know that zur Hausen did not get the details quite right at the time, since

the HPV causing genital warts are of a different type than that causing cervical cancer. Nevertheless, this intervention shifted causal thinking about cervical cancer from HSV2 to HPV, an entirely different family of viruses.

In subsequent years a number of studies by the group of zur Hausen followed. In 1983, the use of molecular hybridization techniques proved the most definitive in identifying specific HPV types in cervical cancer biopsies thus strongly supporting causal relation. The etiologic link remained, nonetheless, controversial until 1986 when the publication of *Viral Etiology of Cervical Cancer* closed the debate about etiology and signalled scientific consensus (Peto and zur Hausen 1986). After some years, also the epidemiological validity of the link between HPV and cervical cancers was demonstrated: in 1995 the IARC declared two HPV types (16 and 18) to be carcinogens in humans (Walboomers et al. 1999; Muñoz et al. 2003; Muñoz et al. 2006).

3. HPV: classification and epidemiology

Since the pioneering studies of zur Hausen and colleagues, a lot about HPV is now known: its mechanisms of action, the role of the infection in the development of cancer at the cervical and other sites, as well as its epidemiology. At present, nearly 130 types of HPV have been identified after cloning from clinical biopsies. They can be broadly grouped into cutaneous types and mucosal types according to their preferred tissue tropism. HPVs are quite similar in their structure and genome organization. HPVs are small (8000 base pair), non-enveloped, double-stranded DNA viruses enclosed in an icosahedral capsid that, in turn, is composed of two molecules (L1 and L2). The HPV genome, moreover, encodes, six early proteins (E1, E2, E4, E5, E6 and E7)

that are necessary for viral DNA replication and for the production of new virus particles within the infected cells (Muñoz et al. 2006). Lastly, the HPV genome contains a non-coding region, called long control region (LCR), which is necessary for activities like regulation of gene expression and the replication of the genome (Scheurer, Tortolero-Luna, and Adler-Storthz 2005; IARC 2007; Stanley 2010).

The cutaneous types are typically found in the general population and cause common warts. The mucosal HPVs are further classified into low-risk and high-risk types, referring to their oncogenic potential. The main low risk types are twelve (6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81, 108) (Muñoz et al. 2006). Among them, the most common are HPV 6 and 11, detected in about 90% of benign anogenital warts. The HPV types most frequently giving rise to persistent infection in the host and involved in the etiology of cervical (and other) cancers are defined high risk, and are fifteen (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, 82). Among the high-risk types the predominant ones are HPV 16 and 18, and together they account for 70.7% of cervical cancers. All high-risk types account for 99.7% of all cervical cancers worldwide (Muñoz et al. 2003).

	Low-risk HPVs	**High-risk HPVs**
Strains	**6, 11,** 40, 42, 43, 44, 54, 61, 70, 72, 81, 108	**16, 18,** 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, 82
Pathology	Genital warts, Recurrent Respiratory papillomatosis	Cancers: cervical, vulvar, penile, perianal, vaginal, anal, head and neck

Table 1: This table categorizes low and high-risk HPV types and related pathologies. The types in bold are those targeted by currently available vaccines

HPV, as said, is a sexually transmitted virus. Transmission occurs mainly through skin-skin contact at the genital site. This means that a complete penetrative sexual intercourse is not needed for person-to-person transmission of the virus, although it renders it more likely to occur. Numerous epidemiological researches done in the last fifteen years have shown that HPV is the most common sexually transmitted infection worldwide (Trottier and Franco 2006). For instance, the American Cancer Society estimates that around 5.5 millions Americans newly acquire the infection every year (2.4% of the total population), and that 20 millions are currently infected by at least one type of HPV (15% of the population). It is further calculated that there is a 75% chance for an individual to get HPV in his or her lifetime (Baseman and Koutsky 2005). A meta-analysis of 194 studies published from 1995 to 2009 that included more than 1 million women found 11.7% of them infected with at least one type of HPV. The study shows highest numbers of infections in Sub-Saharian Africa (24%), Eastern Europe (21.4%), and Latin America (16.1%). Among them, the most risky oncogenic types (HPV16 and 18) were also the most common (Bruni et al. 2010). The age-specific distribution of HPV infections seems to follow a common path in many areas. It has been observed, in particular, a first peak of infections at younger ages (<25 years) after sexual initiation. After the first peak, numerous epidemiological studies document a consistent age related decline followed by a second peak among individuals 45 years or older (reviewed in Tota et al. 2011).

A number of studies also calculate the prevalence of the virus in the male population. A meta-analysis of 12 studies done between 1991 and 2005 shows that percentage of infections in the various cohorts tested varied between a

minimum of 2.3% up to a maximum of 34.8% (Partridge and Koutsky 2006). A two-year study, done by Partridge's group in a cohort of 240 male university students in Washington, found 62.4% of the participants infected with at least one HPV type. Moreover, 47.9% of the total participants were found infected with a high risk HPV type (Partridge et al. 2007). The study has some limitation, indeed the number of people tested and the specificity of their background does not allow for broad extrapolation about the prevalence of HPV in the general male population. It is, however, remarkable that these numbers almost double those found in a similar population of girl university students. These data, together, suggests that rates of infections in men are at leas as high as those observed in women (Tota et al. 2011) and, more generally, that HPV infection is very common in sexually active individuals.

4. Natural history of HPV infections and cervical cancer pathogenesis

To understand HPV infection and its link to cervical cancer, it is important to briefly illustrate the main steps in cervical cancer progression. In 1973 Richart introduced a three level system of classification for the different stages of progression of this cancer, called the cervical intraepithelial neoplasia (CIN) system. The CIN categories are (Richart 1973):

- CIN1: mild dysplasia in which abnormal cells only occupy the basal half of the epithelium of the cervix
- CIN2: moderate dysplasia, the abnormal cells occupy two thirds of the epithelium
- CIN3: severe dysplasia, almost full thickness involvement of the

epithelium by abnormal cells.

The final stage of progression is the tumour itself, called invasive cervical cancer. Cervical cancer can be divided into further stages depending on whether it is localized in the cervix or it extends to adjacent or distal organs (metastasis).

As said above, HPV is a necessary, still not sufficient, cause of cervical cancer. This means that, although nearly the totality of cervical cancers is triggered by a persistent infection with oncogenic types of HPV, not all infections eventually undergo malignant transformation. In most circumstances, indeed, the immune system of the host is able to clear the lesion within three years, and this is estimated to happen in the 90% of the cases of infection (Cooper et al. 2003). However, in a proportion of women it will persist and progress. High risk HPV infection that persist for more than three years are unlikely to resolve naturally and convey significant risk of development into high-grade intraepithelial dysplasia (CIN2 and CIN3). The latter, if left untreated, are very likely to progress into cancer (Moscicki et al. 2006). In their review of the published literature about the natural history of HPV infections Wright and colleagues (2003) show the proportion of infections that go through the different stages. In particular they propose that:

- 43% of CIN2 regresses, 35% persists as CIN2 and 22% progresses to CIN3 or invasive cancer

- 32% of CIN3 regresses, 56% persists as CIN3 and 14% progresses from CIN3 to cancer

These numbers suggest clearly that HPV, though necessary, is only one factor in the development of cervical cancer. Multiple studies have identified different

host factors and behavioural factors that play a role in the persistence of HPV and the risk of progression to precancerous lesions. The immune status of the host, for instance, has been cited as particularly relevant. As an indication of this, it has been observed that women who are immunosuppressed have two to three times the rate of HPV and high grade CIN compared with women who are not immune compromised (Cox 2005). Further evidence of this connection is provided by the high rate of HPV persistence and progression in HIV positive patient (Wiley and Masongsong 2006). Among the behavioural co-factors, instead, it is often cited smoking, use of oral contraceptive, and other sexually transmitted diseases such as *Chlamydia trachomatis* (reviewed in Moscicki et al. 2006). Cervical cancer pathogenesis is thus a very complex process that needs HPV to initiate and other, less specified, factors to progress. Cervical cancer, in synthesis is a rare consequence of a common infection.

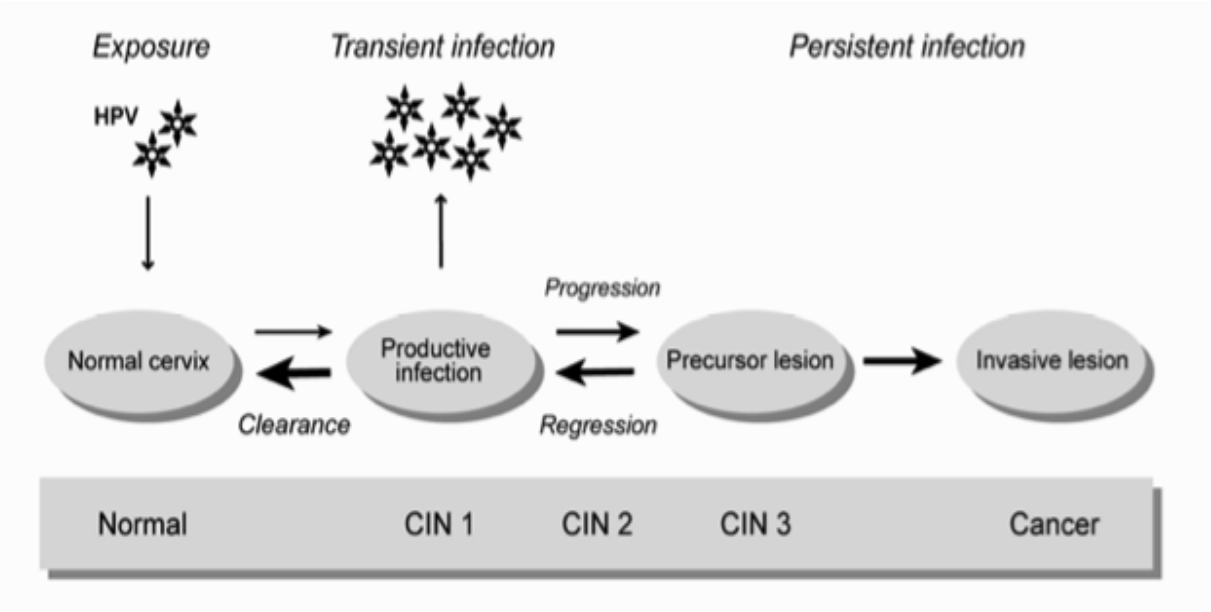


Figure 1. Cervical cancer pathogenesis. (Stanley 2010)

5. HPV vaccines: efficacy and safety data

In 1992 Kirnbauer and colleagues, from the National Cancer Institute, published a study in the *Proceedings of the National Academy of Sciences* that paved the way for the development of HPV vaccines. They observed that the proteins of the HPV capsid (especially L1) were able to self-assembly in vitro in what they called *Virus Like Particles* (VLP). VLP were in all respects identical to HPV, but they lacked the genetic material necessary for viral replication. They also observed that such VLP induced neutralizing antibodies, so they claimed: "This type of L1 preparation might be considered as a candidate for a serological test to measure antibodies to conformational virion epitopes and for a vaccine to prevent papillomavirus infection" (Kirnbauer et al. 1992, 12180).

Since then, pharmaceutical industry efforts have been concentrated in the clinical testing of a prophylactic vaccine against HPV. So far, two VLP HPV vaccines have been produced and later licensed by many regulatory agencies worldwide, such as FDA and EMA, between 2006 and 2009:

- A quadrivalent vaccine (called Gardasil, produced by Merck). In this vaccine the L1 protein of the capsid are produced in recombinant *Saccharomyces cerevisiae* and generate VLP of HPV 6, 11, 16, and 18.

- A bivalent vaccine (called Cervarix, produced by Glaxo-SmithKline). In this vaccine the L1 proteins of the capsid are produced with the system of expression of the vector *Baculovirus* and mimic HPV 16 and 18.

Both vaccines offer some cross-protection against other high-risk strains of HPV and are given in a series of three shots over six months. Both vaccines, moreover, have shown high profiles of safety and efficacy in randomized clinical

trials. Some studies need to be mentioned. As for Cervarix the phase III clinical trial that proved its efficacy was:

- *PATRICIA study* by Paavonen (Paavonen et al. 2007; Paavonen et al. 2009). This study was conducted in Australia, Belgium, Brasil, Canada, Finland, Spain, Germany, Italy, Mexico, Philippines, Taiwan, Thailand, USA, and UK and involved more than 19,000 thousands women aged 15-25. Criteria for enrolment in the clinical trial were: general good health status, no prior history of HPV infection and no cervical lesions at the moment of enrolment. Of these women, only 15,626 completed the trial and were followed up for six years. 7788 women were given the vaccine and the remaining a placebo. Endpoints for evaluating efficacy were CIN2 or CIN3 associated with HPV 16 and 18. After six years only 2/7788 women in the vaccine group versus 21/7838 in the placebo group developed intraepithelial lesions associated with the HPV viral types covered by the vaccine. In the language of clinical research the vaccine thus showed an efficacy of 90.4%[12].

As for Gardasil, the phase III clinical trial that proved efficacy was:

- FUTURE-2 (Garland et al. 2007). This study was conducted in thirteen countries and enrolled more than 12,000 women aged 16-26 (6087 in the vaccine group and 6080 in the placebo group) followed up for six years. Criteria for enrolment were like above: good health status, no prior history of infection and no cervical lesions at the moment of enrolment. Endpoints for evaluating efficacy were CIN2 and CIN3 related

[12] An efficacy of 90.4% does not mean that the vaccine is effective in roughly 9 out of 10 women. It means that 9 out of 10 of the clinical endpoints (CIN2 and CIN3) where observed in the placebo group.

with the types covered by the vaccine. In the vaccine group 5306 participants completed the trial and, among them, only 2 were found with HPV 16 or 18 associated intraepithelial lesions versus 63/5262 in the placebo group. The vaccine's efficacy was thus 96.9%.

The quadrivalent vaccine, moreover, has proved to be efficacious with similar results also for the prevention of anogenital lesions in men (Giuliano and Palefsky 2008; Giuliano et al. 2011). Both vaccines have hence high efficacy scores. There are no efficacy data in the age group 9-14. Indeed, to measure vaccine efficacy it is necessary to perform invasive examinations of the cervix to observe whether there are CIN2 or CIN3 lesions. These procedures were clearly unethical for such young girls. Although there are no such data, the trials showed that in the age group 9-14 vaccine-induced immunity was actually higher than in older women. This fact allowed the inference that the vaccine would have high efficacy scores also in this age group that is also the one identified by the WHO as the preferential target for vaccination (World Health Organization 2009).

Another unknown about the vaccination is the duration of the acquired immunity. In fact, the follow up in clinical trials was only of 6-7 years. However, no reduction in the specific antibodies was observed. Also in this case the inference was that immunity can be long lasting, but no direct proof exists for that.

As with every drug, however, both vaccines might give rise to adverse reactions after injection. In the clinical trials mentioned, both vaccines have shown to be well tolerated. The most frequently reported adverse event, in the vaccine and placebo group, was pain at the injection site. The rate of systemic adverse

events was also comparable in the two groups, it being below 0,1% (Harper et al. 2004; Harper et al. 2006; Reisinger et al. 2007).

Post-marketing surveillance by *The Centers for Disease Control and Prevention* (CDC) shows that, as of September 2011, more than 40 million doses of Gardasil have been distributed in the US and that only in about 0.05% of cases adverse reactions have been reported to VAERS (Vaccine Adverse Events Reporting System). Of this 0.05%, 92% were non-serious events, such as pain and swelling at the injection site, headache, nausea and fever. The remaining 8% were serious. In particular, a number of cases of Guillain-Barré syndrome (a rare neurological disorder that causes muscle weakness) were reported. However, the incidence of such a syndrome in the vaccinated population does not exceed that in the general population, thus excluding a direct causal link with Gardasil[13].

6. HPV-related disease burden

I have already mentioned above that cervical cancers account for the majority of the HPV-related disease burden. As said, the HPV types covered by both vaccines, that is HPV 16 and 18, account for 70.1% of cervical cancers worldwide, the other high-risk types are instead responsible for all the other cases. Using the web database of the WHO HPV Information Centre[14], I will now

[13] These are the official data reported by *The Centers for Disease Control and Prevention*. They are publicly available at: http://www.cdc.gov/vaccinesafety/vaccines/hpv/gardasil.html (Last access: 30th October, 2011).

[14] The WHO database aggregates data from official reports by WHO, United Nations, the World Bank, and IARC Globocan 2008. These data sometime diverge from others provided by different institutions. I will cite the relevant sources accordingly. The WHO database is publicly searcheable at: http://apps.who.int/hpvcentre/statistics/dynamic/ico/DataQuerySelect.cfm (Last access: November 2nd, 2011).

provide data on cervical cancers on those countries that will be part of the ethical analysis in the remaining part of the thesis: that is US, UK, and Italy. These data are updated to 2010.

In the US current estimates indicate that every year 11069 women are diagnosed with cervical cancer and 3869 die from the disease. Of these cancers, 76.6% are caused by the HPV 16 and 18, the types covered by the vaccine. Cervical cancer ranks as the 13th most frequent cancer among women and the 4th among women aged 15-44. According to the same source, the annual incidence of cervical cancer is of 7 per 100,000 women.

In the UK every year 2890 women are diagnosed with cervical cancer and 1111 die from the disease. 79.1% of these cancers are attributed to HPV 16 and 18. Cervical cancer ranks as the 11th most frequent cancer among women in UK, and the 2nd most frequent cancer among women aged 15-44. The annual incidence is of 9.3 per 100,000 women.

In Italy, finally, every year 2880 women are diagnosed with cervical cancer and 906 die from the disease. 71.8% of these cancers are caused by HPV 16 and 18. Cervical cancer is the 16th most frequent cancer among women, and the 4th among women aged 15-44. The annual incidence is of 9.4 per 100,00 women.

HPV 16 and 18, moreover, are now recognized to be involved in the aetiology of several cancers other than cervical ones. Some of these are female-only cancers: the strains are believed to be involved in 40% of vulvar cancers and 90% of vaginal cancers. But some of them are not: the strains are believed to be involved in 50% of the male-only cancer of the penis, in 85% of anal cancers, 33-72% of oropharyngeal cancers and 10% of cancers of the larynx (Zur

Hausen 2002)[15]. As said above, HPV 6 and 11 cause 90% of genital warts in both females and males. Although benign, these lesions require repeated treatment and their incidence is far higher than any of the abovementioned cancers (in the US, it is calculated to be around 250 per 100,000 per year and to be most common in men) (Giuliano 2007).

All the data presented in the last sections provided the evidence for several countries to take action against HPV. Like all vaccines HPV is more efficacious when administered before the subject encounters the infective agent. For this reason all those countries that have devised HPV immunization policies as a means to prevent cervical cancer have identified 11-13 year old girls as the preferential target group for the immunization. Indeed a population wide administration of the vaccine, combined with current cervical cancer preventive strategies, has the potential, if successfully implemented, to drastically reduce the incidence of (and perhaps eliminate) cervical cancer. I will discuss the ethical dimension of some of these policies models more extensively in chapter four. Before doing that, however, I need to provide more background about vaccination, its political context, and the ethically sensitive issues it touches upon. The second part of this chapter is therefore dedicated to unpack these issues.

[15] I will give a more detailed account of these cancers below (*infra* chapter 5).

Part 2. Preventing infection for avoiding cancer: the ethical dimensions of HPV immunization.

7. HPV a new tool for an old preventive job: vaccination as an ethical problem

So far I have discussed of HPV vaccination as of its potential benefits with regard to cervical cancer prevention. The way for its policy implementation and its full effects on women's health be appreciated, however, is not as smooth as one may suppose. As with arguably all innovations, HPV vaccination encounters appraisal but also political hostility as well as ethical and legal issues that need to be taken into account for correct policy implementation. Moreover, although HPV vaccines are extremely innovative as technological artefacts, they are less so as public health technologies. Vaccination indeed is a public health activity well entrench in several health systems, with its own dedicated infrastructures, professional competences, policy requirements accompanied, of course, by ethical problems and political obstacles.

The history of vaccination is long. It is characterized both of remarkable successes in terms of the health and welfare benefits accrued at the individual and collective level, and of stark oppositions at the political level. A brief overview of these aspects is important in that it will permit to elucidate, along the lines of this work, in what respects current policies encounter similar problems and to what extent, instead, they put forward novel specific issues. Therefore, before starting with the peculiarities of the case under consideration,

it is important to give an overview also of the analogous problems that previous vaccination policies have encountered in the course of the last century.

As the historical record shows, vaccination is one of those medical and public health technologies that have most ameliorated population health in the last two centuries. As the authors of a leading textbook in vaccinology write: "With the exception of safe water, no modality, not even antibiotics has had such a major effect on mortality reduction and population growth" (Plotkin and Plotkin, 1994). The great impact vaccines had in public health is easily ascertainable. Small pox, once a terrible scourge for humanity, has been eradicated by concerted international efforts by the end of the 1970s. Thanks to these coordinated efforts, WHO was able to announce in the August of 1980, that small pox was finally eliminated from the globe. The sharp decline of poliomyelitis, a poliovirus induced disease that caused as much as 20,000 cases of paralyses each year in the US until the mid 1950s, is another case in point. After vaccine introduction in 1955, indeed, polio has been virtually eliminated in several industrialized countries and is now endemic only in a few areas of the world. Similar stories can be told about diphtheria -whose incidence has been drastically reduced since the 1960s – and, with differences observed in various countries, tetanus, pertussis, tuberculosis, measles, mumps and rubella.

Although all these diseases are different in terms of their epidemiological profiles, pathogenesis, and severity, all, except tetanus, share an important feature: they are transmissible from person to person through casual routes (such as airborne droplets, saliva, etc.). This very simple fact permits the establishment of another, equally simple, epidemiological phenomenon: if enough people acquire immunity against the infective agent, the likelihood of an

epidemic falls down to the vanishing point. Humans can acquire immunity against these infective agents either naturally, by developing specific antibodies after having encountered the disease, or by induction, through vaccination. Vaccination thus offers a dual benefit: one at the individual level, by conferring immunity without the harmful complications that the naturally acquired disease may give rise to; another at the population level, when enough people are vaccinated so to reach the herd immunity threshold. How large a proportion of individuals need to be vaccinated in order to achieve the herd immunity threshold varies depending on several factors: the infectivity of the agent (that is, how many contagions occur for every infected individual), the efficacy of the vaccine, and the structure of the population. No matter the specific epidemiological details, however, it is important to underscore that it is the possibility of creating herd immunity effects that drove the establishment of mass vaccination policies in several countries in the last century. Herd immunity provides a good that extends well beyond individual's enjoyment of personal protection. It is a good that protects the whole community, no one excluded. A second feature that called in favour of state-backed vaccination is the attractive cost-benefits profile immunization policies have. Since the 1970s, health economists have justified vaccination through cost benefit analysis. Cost-benefit analysis is a technique for quantifying the value of an intervention by weighing its costs – even included the costs of possible adverse reactions – against the positive outcomes. It resulted that many vaccination programmes were a good investment for money. Vaccination programmes, hence, do not only offer the opportunity to avoid human suffering and death, both at the individual and at the collective level, but they do so without huge spending for society.

The possibility of establishing herd immunity so to have population wide benefits in terms of health has long justified the devise of state backed policy actions. The state, indeed, is the best-positioned actor to coordinate collective endeavours properly, and it is one of its recognized functions that of providing benefits and reducing harm to its citizens. What is the right way to do that, however, is an open question and it is not clear whether coercion is ever justified. In infectious diseases control coercion has taken many forms. It has involved: the deprivation of liberty, like in the case of forced quarantine; the imposition of pecuniary sanctions, like in Italy where until 2001 parents who refused to immunise their children were fined with sanctions up to €150; and the refusal of enrolment in nurseries and schools, both in Italy (Moran, Gainotti, and Petrini 2008) and the US (Gostin 2008, 383). Coercion, moreover, has been exercised through the formal mechanisms of law, as well as through informal means, like pressure from authoritative figures like paediatricians or from health promotion messages stigmatizing the failure to vaccinate. These measures have sometimes been contested as being too far-reaching into a sphere, such as that pertaining to medical matters, which, to some, should be left instead to the conscience of individuals and their autonomous choices. Arguably, coercion may be appealed in many contexts to protect the community and its members, it is not clear, however, when it is ethically acceptable, nor a consensus about this issue is found in moral or political philosophy (see Dworkin 1978 and Gaylin and Jennings 2003 for two different views on this general issue. See also *infra* chapter 1). No matter, for now, how one resolves the philosophical issue, coercion in its various forms has long been contested as an appropriate tool in the vaccination contexts.

The historian of medicine John Colgrove (2006, 1) reports a case of a Brooklyn citizen who, in 1931, appealed to the New York City's health commissioner lamenting for the exclusion of his son from school because he was not immunized against small pox as required by law. As he claimed "It is revolting, to say the least, that I must have diseased animal matters injected into the blood of my son before he can receive an education." The opposition against vaccines, it must be said, was not so much guided by feeling of disgust for foreign matters to be injected into the 'blood', but perhaps more by a strong cultural ethos against state paternalism present in consistent segments of the population in many western countries. Anti vaccination activists in the United States have sometimes reported John Stuart Mill's argument in support of their thesis that parents should let be free to decide whether to vaccinate their children. In one of the opening passages of *On Liberty* (1859), the English utilitarian philosopher and one of the main voices of liberal political philosophy, says:

> That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral is not a sufficient warrant. He cannot be rightfully compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinion of others, to do so would be wise, or even right. (Mill 2003)[16]

The argument against vaccination was thus that non-vaccinators are only putting themselves at risk, and not others. Moreover, it can be claimed, the ones who are at risk would be those that are not immunized themselves. Although these remarks may sound reasonable, the harm principle also supports the legitimate use of state power in immunization contexts. In fact, vaccination is

[16] This quotation was already given in chapter 1 of this work.

not always one hundred per cent effective. This means that there will always be people that, despite vaccinated, will not develop the required immunity and thus will be at risk of contracting the disease. Moreover, for some people vaccination is contraindicated on medical grounds; either because of their weak immune systems or because they have proven allergies against one of the components of the vaccine. Finally, the vast majority of vaccinations occur during childhood, and so most of the unvaccinated people are kids who have certainly not decided to be unimmunized. Failing to provide herd immunity, hence, would amount to an increased risk of harm in those categories of people. It appears, hence, that the harm principle also justifies strong collective commitments towards herd immunity. In some instances, therefore, also liberal political philosophy provides the conceptual tools for legitimate use of state power as to limit the boundaries of individual liberties.

The legitimacy of, sometimes forceful, state intervention for controlling infectious diseases is not only supported by abstract philosophical arguments, although one can speculate that they inform public reasoning, but by various jurisprudences too. The landmark case in the US is a 1905 ruling of the Supreme Court upholding compulsory vaccination in the state of Massachusetts contested by Mr Jacobson. In *Jacobson v. Massachusetts* the Court states:

"There are manifold restraints to which every person is necessarily subject for the common good. […] a community has the right to protect itself against an epidemic of disease which threatens the safety of its members"[17]

[17] The full text of the ruling is to be found in: (Gostin 2002, 206–212)

As the legal scholar Lawrence Gostin notes, these rulings have permitted, in the US context, to achieve rates of immunization (more than 95%) as high or higher than other developed countries (Gostin 2008, 376) thus creating herd immunity against several contagious diseases for the protection of all. The use of state mandates, however, is not exclusive of US, also in Italy some childhood vaccination were required by law (polio, hepatitis B (HVB), diphtheria, and tetanus) until 2001 (Decreto del Presidente della Repubblica 22 Dicembre 1967, n. 1518 1968; Parlamento Italiano 2001), and also in this case the use of this measure has allowed to achieve high levels of population protection. Italy, for instance, was one of the first European countries in which polio was eliminated (1982), well before that the same result was achieved in the whole European region (2002)[18].

Another argument in favour of strong state-backed intervention for the control of infectious diseases comes from concerns about social justice. The use of mandates may be better suited to reach all those people that are underserved by state preventive services. As John Colgrove notes (ibid. 11-13), while at the beginning of the 20th century decisions not to immunize were seen solely as expression of sheer laziness, ignorance or apathy, in the mid 1950s these behavioural explanations began to be supplanted by considerations of equity and justice. Surveys found a gradient in vaccine uptake along the lines of income and education, with those at the bottom of the scale much less likely to be protected than those at the top. This wide gap in vaccination coverage justified the introduction of what he calls a 'second generation of laws' in the US (ibid. 149-185). A number of states began to condition school entrance upon

[18] Data drawn from the Italian Ministry of Health (Ministero della Salute) website: http://www.salute.gov.it/malattieInfettive/paginaInternaMenuMalattieInfettive.jsp?id=645&lingua=italiano&menu=vaccinazioni (Last access: 23rd October, 2011).

immunization to remedy health disparities with the tools of the administrative state. The use of the schoolhouse for controlling diseases, also adopted in Italy and France for the vaccination against Hepatitis B and in Australia for several childhood immunizations, has another attractive feature beyond equity. The schoolhouse, indeed, is a public space in which infections can be transmitted easily and epidemics take place. It is thus an attractive locus for prevention too. Demands for group protection have therefore enmeshed in policy practice with broader concerns for an equitable distribution of public health benefits in areas at risk of social deprivation.

The history of vaccination can be continued for long, perhaps with numerous ramification as we start to make more precise distinctions among different diseases, different legislations and broader cultural aspects that characterize each country and each historical context. What it is important to notice for the purposes of this work is that, by and large, vaccination as a public health strategy has reached in many countries political stabilization and robust social acceptance. Clearly, this claim needs to be taken with due caution. From time to time, contestations emerge alleging severe adverse reactions some vaccines supposedly bring about. Sometimes these claims are proven false by public health authorities and painstaking activities are then required to reassure the public. Sometimes, instead, severe adverse reactions are confirmed, such as in the case of the oral polio vaccine (OPV) and a vaccine induced form of paralytic poliomyelitis, and the use of a certain vaccine is discontinued. Despite these complexities, however, it is fair to say that vaccination against some contagious diseases (like polio, measles, diphtheria) is now an accepted social norm as high vaccination coverage, also in countries in which there are no mandates, shows.

Indeed, high uptakes also permit several states to rely on voluntary policies, like in the UK, to relax vaccination requirements by allowing liberal exemptions for religious reasons or deeply held moral convictions, like in the US (Salmon et al. 2006), or to devise national plans for repealing mandates and promote voluntary participation, like in Italy (Parlamento Italiano 2001).

The stabilization of vaccination as a social practice indicates an achieved equilibrium between individual concerns for autonomous choice in medical matters and the obligation of the state to protect collective goods. Currently high immunization coverage allows protection to all and also permits the toleration of "a small rump of voluntary non-immunizers" (Dare 1998, 147). Vaccination policies actively promoted by the state, moreover, do generally also support equitable access to public health benefits across the socioeconomic gradient and, perhaps, this is another reason why many find these endeavours morally justified. Social stabilization in practice, however, does not imply that the tension between individual and group interests is also resolved in theory, nor that coercion, in various forms, could not be reconsidered a viable options should the collective good be under threat. Moreover, appeals to social justice may not always be considered sufficient for justifying strong state-backed interventions in other vaccination contexts.

Otherwise stated, the deep-seated problems with vaccination do not disappear after collective goods are stable enough, they may be reignited in novel forms when a new vaccination technology enters the public health scene with its prospective, and yet unknown, outcomes. HPV vaccination fits nicely with this description, and to the exploration of its peculiarities I now turn.

8. HPV vaccination: the political context

In the previous section I have noticed how vaccination as a public health technology has reached, not without obstacles, robust acceptance that guarantees equilibrium between demands for respect of autonomy and individual liberties, on the one hand, and group protection, on the other. I have also noted how, despite differences to be observed in the political culture of each country, this process of stabilization has relied on a host of legal and philosophical means justifying liberty limiting state interventions for community protection in some cases. Moreover, I have indicated how the 'harm principle', at least under some interpretations, justifies these interventions also within the boundaries of classical liberal thinking. A further element that has supported the moral legitimacy of state-backed interventions in infectious disease control have been concerns for social justice; that is, the realization that concerted state action, also through the use of various forms of coercive strategies, were necessary to reach the population equally.

In what follows I show how HPV immunization reopens, in both old and unprecedented forms, the question as to how rightly balancing individual concerns and public interest in the vaccination context. I first describe how those tensions played out at the level of public debate. To do this, I show how the demands for respecting parental autonomous choice with regards to medical decisions were put forward vis à vis the population benefits that HPV vaccination could bring about. This contrast emphasizes worries about safety and long-term duration of the vaccine and, more generally, issues of citizen's trust towards the public health system. In the face of it stands the disproportionate burden of cervical cancers carried by women at the bottom of

the socioeconomic gradient and the need to ensure equitable access to the intervention. Clearly, the framing of public debates is always specific to the contingencies of the social context and political cultural in which it arises. Since I am aware of the nebulous boundaries of public discourses though, I will only focus on those themes that provide background for the identification of the morally sensitive issues that will inform my ethical analysis. After that, I will put analytical order into the issue by specifying what are the core values at stake in this context, and how they contrast.

HPV vaccination introduces into a morally sensitive context such as girl's health, their sexuality, and claims for respecting the autonomous choice of parents in the decision of such issues without governmental intrusions. This issue has ignited a debate, especially in the US and Canada, as to whether is right use of state's power to endorse for widespread distribution a vaccination for sexually transmitted diseases in such young age groups. In both countries, indeed, several bills were issued after vaccine approval for mandating immunization to 11-12 year old girls as a condition for school entrance. The issue, generally put forward by religious conservatives, centred on the fear that the vaccine could have sent a wrong message to girls by giving a false sense of security that, in turn, could have led them to engage into promiscuous sexual lives. To some, such a vaccination, especially if forcefully endorsed by the state, could have undermined abstinence based prevention messages and condoning pre-marital sex. As it appears, once the whole debate was stripped a bit of its emotional charge, the official positions of religious conservatives became more nuanced and informed. As we read in the official statements issued by the main religious organizations that had initially cast some doubt on the vaccination,

what they opposed was not vaccination as such, but the use of legal means to ensure its wide acceptance. For instance, *Focus on the Family*, a Colorado based organization providing Christian guiding about issues pertaining marriage, parenting and the family, states: "Focus on the Family supports widespread (universal) availability of HPV vaccines but opposes mandatory HPV vaccinations for entry to public school. The decision whether to vaccinate a minor against this or other sexually transmitted infections should remain with the child's parent or guardian" (Focus on the Family 2006). A similar organization based in Idaho, *Family Research Council*, after emphasizing that "media reports suggesting that [the organization] opposes all development or distribution of such vaccines are false" states that "parents have an inherent right to be the primary educator and decision maker regarding their children's health" and thus they oppose any measure that would legally require vaccination (Gaul 2006). Both organizations, moreover, claim that both healthcare providers and parents have the duty to show that the most effective preventive measure against all sexually transmitted infections is sexual activity in the context of one faithful and monogamous long- term relationship inside marriage. Similar arguments, although the debate never reached the same intensity it had in the US, have been observed in the UK. As reported by the health editor of *The Guardian* commenting on the reasons for parental vaccine refusal: "some may have concerns that allowing vaccination may promote promiscuity, because the cancer-causing virus which the vaccination targets is passed on in sexual intercourse." [19] Religious conservatives, moreover, emphasized, this time in tune with a large group of people of heterogeneous

[19] http://www.guardian.co.uk/society/2008/apr/25/health.cancer (last access: April 26th, 2010)

political and philosophical persuasions, that requiring vaccination as a condition for school entrance, as it is the case for several childhood vaccinations, does not meet the historical justification for mandating immunization in the US (Gostin and DeAngelis 2007; Javitt, Berkowitz, and Gostin 2008). As I explained above, two major justifications for mandating immunization and conditioning school entrance upon it had to do respectively with the right of the community to defend itself in case of a public health necessity, and in the identification of the schoolhouse as space in which disease transmission can occur. Differently from the historical cases that justified mandates for small pox and polio, hence, school attendance does not constitute, per se, an increased risk of HPV infection. That is to say, while polio and measles spread casually, HPV infection requires intimate sexual contact to occur and can thus be prevented by a variety of means.

In the HPV vaccination case, concerns for parental autonomy, demands for improving population health and ensuring equitable access to preventive health services have also enmeshed with a climate of suspicion about the real motivations of the campaign. In 2007, shortly after FDA approval, the former Governor of Texas Rick Perry issued an executive order, thus bypassing legislation, to mandate HPV vaccination to girls entering sixth grade. Hot contestations ensued this unusual institutional move. As a consequence, Perry, now running for the 2012 Republican Presidential Primaries, had to repeal the executive order and leave the matter to the Texas House of Parliament. Amid a political firestorm, critics charged that a Merck lobbyist, who was former chief of his staff, influenced the president's decision. Almost contemporarily, newspapers' reports divulged that the same vaccine's manufacturer company

had given heavily to *Women's in Government* - an advocacy organization made up of women legislators who support bills aimed at advancing women's issue – who made a priority to introduce HPV-related legislation (Colgrove 2010). Coupled with the high price of the vaccines, which in Europe is € 515,92 for the full series of three shots, these critics alleged the campaigns were responding to the interests of Big Pharma, rather than to the health needs of the population. These concerns crossed the ocean and reached also Europe. In Italy, for instance, some anti-vaccination activists labelled the introduction of HPV vaccination a "stupro sanitario" (public health rape)[20], and two anti-vaccination paediatricians supporters of homeopathic alternatives alleged suspicious conflict of interests in a monograph[21].

In a less suspicious vein some have questioned the necessity of HPV vaccination campaigns. Indeed, cervical cancer is one of those few cancers in which prevention is possible through screening, the so-called PAP smear. The latter has contributed to a sharp decline in rates of cervical cancers in the last forty years from 32 cases per 100,000 women in the 1940s to 8.1 cases per 100,000 women in current days in much developed countries (Peto et al. 2004; Howlader, Noone, and Krapcho 2011). Thus some have claimed that spending public money on the vaccine is not a public health necessity, and it could also avert individual attention and public resources from cervical cancer screening programmes (Lippman 2008). This issue should require even more caution, if data about long-term duration of the vaccine are taken into account. As

[20] Document to be found at: http://www.newmediaexplorer.org/rinaldo_lampis/2008/04/08/vaccino_antipapilloma_hpv_stupro_sanitario.htm (Last access: November 1st, 2011)

[21] The title of the book reads: *Vaccinare contro il papillomavirus? Cosa dobbiamo sapere prima di decidere* (Vaccinating against papillomavirus? What we should now before deciding) (Gava and Serravalle, 2008)

anticipated above, HPV vaccines clinical trials have only followed up women in the protocols for 6-7 years. Although the studies show no reduction in vaccine-induced immunity after that time frame (Paavonen et al. 2009; Garland et al. 2007), it cannot be excluded that immunity can, at some point, wane thus rendering early vaccination less attractive.

HPV vaccination programmes as put into their political context underscore a bag of different intuitions and concerns sometimes pulling to opposite directions. A look at all these complexities may give the impression that a balance will not be easily found, and that social stabilization will occur through unpredictable chains of negotiations among different interests. Although I agree that the trajectory of political processes leading to the stabilization of vast social phenomena like vaccination does not lend itself to ready made predictions, I propose that framing the issue in terms of the moral values at play can help social reflexivity and foster ethically sound public discourses. In what follows I will thus begin such an attempt, and present the core values that emerge from the HPV context. A deeper exploration of how different policy models can best be put in balance those values will instead be part of the remaining parts of this dissertation.

9. HPV vaccination: morally relevant interests and ethical trade-offs

As shown in the preceding pages the phenomenology of vaccination, in general, and of HPV vaccination**,** in particular is complex. Despite complexity, four sources of moral concern surface the debates, all with *prima facie* validity. They are: the interest of parents to autonomously decide about issues pertaining to the healthcare and preventive education of their children, the interest of public

health institutions to fulfil their duties of beneficence at population level, the interest in implementing equitable vaccination programmes, and an interest in the efficiency of the intervention in achieving the goals and doing it without waste of resources. On top of these sit demands for better health, both at the individual and population level. In this section I analyse the scope of these interests and why they are all morally relevant. That is what they consist of and why are they important. After this characterization, I will indicate how these interests may come into contrast in the HPV vaccination context.

Autonomous choice. Concerns about vaccination centre, primarily, on an interest that parents have in making free and autonomous choices about their children's care and education. The traditional understanding of autonomy in bioethics conceives of it as comprised of, at least, two elements: freedom and agency. Freedom means, at a minimum, absence of external interference and limitations. Agency, instead, refers to the ability to comprehend the action to be taken, its alternatives, and consequences as well as competence to make a decision (Beauchamp and Childress 2009, 100). The first element, in our context, involves the idea that parents, or guardians, are well-positioned actors to understand what is best for their children without interference. Parents, hence, have a morally grounded interest in vaccinating their kids if they are convinced that intervention is what is best for them. Although population concerns may sometimes inform their choice, it is fair to assume that their primary concern is directed to their children overall welfare. For a decision to be really autonomous, however, parents also have an interest in being provided with all the relevant information needed so that their consent is truly informed and voluntary (Faden and Beauchamp 1986). In the case of HPV vaccination,

moreover, another interest emerged as particularly relevant. That is, the interest parents have in providing their children with the moral and sexual education they see fit without outer interference. This involves freedom of decision as to whether, when, and by what means to expose their children to sexual education. Some parents may value premarital abstinence and want to educate their children as to understand its importance. Some parents may not value abstinence as such, but still want to introduce their children to these issues gradually and in the family private sphere. Other parents, instead, may want their daughters and sons to experience freely their sexual lives without any parental interference whatsoever. Parental autonomy, however, also requires that parents are put in the position to understand the context in which they are asked to decide, and so that accurate information is presented to them. As we can read from a classical account of autonomy: "autonomy is conceived of as a second-order capacity of persons to reflect critically upon their first-order preferences, desires, wishes and so forth and the capacity to accept or change these in light of higher-order preferences and values" (Dworkin 1988, 20). In our context the above quotation suggests that for parents to exercise their autonomy properly – this is the agency aspect - then they need to be given also the tools to critically reflect upon the specific decision-making context in which they are operating. In practical terms, for parents to decide autonomously about the vaccine they need also to be correctly informed about the intervention and whether it really challenges their values.

Beneficence. If it is conceded that parents are, at least at first approximation, the best-positioned actors to decide as to what is in the best interest of their children, it can also be conceded that public health institutions are the best-

positioned social actors to understand how to best address population health needs. Clearly, there can be bad parents who do not take care of their kids. Similarly, there can be public health institutions that badly respond to population health needs. In general terms, however, public health institutions have both the power and knowledge to intervene on population health as to provide benefits and minimize harms as well as a duty of beneficence to do it (Childress et al. 2002). In general terms, beneficence is the moral imperative to act for the benefit of others. In the context of bioethics, beneficence suggests that one of the main medicine's obligations is that of providing benefits to the patients and to support their health and welfare. Generally at home in the context of clinical medicine, beneficence has also its bearing in public health activities. Public health practitioners, indeed, are provided with specific professional competences to bring about or to ameliorate human health at the population level. Sometimes, like in the case of this work, new technologies are produced by scientific research that suggest the possibility to, if correctly implemented, radically change the epidemiological profile of a disease with relevant consequences at the population and at the individual level. It can hence be easily conceded that public health practitioner, and in general all the institutions that operate in the public health sector, have a duty of beneficence towards the general public to implement policies that are for the interest of population health.

Adolescent girls. Even if we grant that parents are the best-positioned actors to determine the interests of their adolescent daughters, it should not be put in one side the fact that also the latters have a stake in this issue. HPV vaccination touches upon very important aspect of every individual's life like sexual health,

sexual identity, and cancer prevention. In this context, HPV vaccination can be seen as one among the tools that may serve to prevent morbidity and avoid premature death. More precisely, adolescent girls have an interest in living a healthy life, avoiding premature morbidity, and being able to develop and pursue their life plans. HPV vaccination can be hence seen as one, certainly among many, intervention that supports the actionability of those plans.

Justice. The third set of interests in public health policies is directed towards a just distribution of their benefits and burdens. Although several theories of justice exist, all agree with a minimal formal requirement. As exemplified by Beauchamp and Childress (2009, 242), the formal principle of justice requires that equals must be treaded equally, whereas unequals must be treated unequally. A chief moral consideration that has long supported mass vaccination programmes is that they have strived to equally distribute the intervention to all citizens, no matter their socioeconomic background. The most relevant consideration, in the vaccination context, is that everyone who is exposed at the risks of infection should be protected. A policy that it is equally accessible to all, hence, would serve the interests of everybody to the maximum benefit of those that stand at the bottom of the socioeconomic ladder. Moreover, public health programmes are, at least in general, among those activities that are needed in a just society to foster fair equality opportunity (see *infra*: chapter 2).

Efficiency. Society places a high moral value in health and healthcare. This realization does not come only from an intuition we all share, but is also epitomised by the percentage of GDP that industrialized countries invest in

healthcare. Despite it, resources to improve health are not unlimited. Health must compete with other desirable social goals, like personal security and education, for resources. As Brock notes (Brock 2004, 201), it is not possible to provide all resources to healthcare or preventive medicine without unacceptable sacrifices in other important social areas. Problems of rationing also occur within the health budget (Beauchamp and Childress 2009, 267-268). Although preventive services are generally less funded than healthcare and biomedical research, this is no licence to use resources improperly. Therefore legitimate demands may arise such that any proposed preventive measure is efficient and that it uses resources properly. One measure for identifying efficiency of an intervention is its cost-effectiveness. The latter is defined in health economics as: "the additional cost required per additional unit of health benefit produced as compared to the next-most-effective alternative" (J. J. Kim 2011, 1760). Whether efficiency should be measured only in terms of cost-effectiveness is open to debate, here I want only to underscore that efficiency has not only an instrumental value but also a moral one. Indeed, an inefficient health policy diverts resources from other health contexts in which the same resources could be better employed. As Gostin (2008, 67) puts it, if public health regulations impose disproportionate expense with modest benefits they forego opportunities for other interventions that may improve community health. So, there might be some individuals raising a legitimate claim as to their interests having been neglected.

Inclusion. As I have shown in the theoretical part of this work, and as it also emerged from the analysis of the political context of the HPV vaccination, it is important to mention the growing interest on the part of the citizens in being

included, in some ways, in the decision of public health policies. The climate of suspicion towards vaccination in general, but as they have also emerged in the HPV context, indeed, can be read in two ways: either as an expression of ignorance and unwarranted distrust towards governments, or as a call for civic membership. There are two reasons why the first option does not hold. First, following that view would probably give rise unintended consequences and radicalize dissent rather than normalize it. Second, if we claim that the people opposing vaccination, or that contest the way in which a particular policy is implemented, are illiterate in science, we would also be bound to claim that those who instead comply do that because of their fine knowledge of public health science matters. If we conceive of dissent, instead, as a legitimate claim of inclusion into public health matters, the social normalization of new vaccines would perhaps be improved. The call for civic membership, however, needs not to be confounded with populism or with a sheer adherence to public opinion. As I have indicated in the theoretical part of this work, part of the job of public health ethics is to found those spaces in which to exercise civic membership in a constructive manner. Moreover, it is important to underscore that the interest towards inclusion should not be supposed to exist only in the most vociferous groups that, from time to time, protest against this or that policy. All those who are affected by a policy - also those that normally have less political power and chance to be heard – have an interest in inclusion. Therefore, the scope of inclusion enlarges also to those that have generally less power and less chance to be heard.

10. Conclusion

The morally grounded interests I have so far presented hold only *prima facie*. This means that sometimes they can be overruled. As the explanation of the vaccination context showed, indeed, these morally grounded interests may sometimes contrast with one another giving rise to ethical trade-offs. I define ethical trade-off as a morally sensitive opposition between competing interests calling for normative resolution. Such trade-offs do not need to arise necessarily, but they may to. For instance, most of the times the interests of parents as to the healthcare of their children may coincide with population health interests as put forward by public health authorities. In other words, parents may very well welcome a vaccination programme and, indeed, in many cases they do. At other times, however, the morally grounded interests may collide, and decisions must be taken as to which of them should take precedence. It is in such situations, that an ethical problem arises. I will not explore all the possible trade-offs that arise among the different morally relevant interests in the HPV context, but only some of them.

In particular, I identify three ethical trade-offs as particularly urgent, and only on them I will focus. They are:

1. Individual choice versus beneficence and population health
2. Individual choice versus justice
3. Justice versus efficiency

Let us explain the content of these trade-offs in order.

The first trade-off arises because, as we saw, there are some parents that oppose HPV vaccination as going against their deeply held moral convictions.

They are afraid that a vaccination policy strongly supported by the state, perhaps even mandated by the law, can undermine abstinence based preventive messages. Other parents, instead, oppose vaccination because they do not see it as necessary to their daughters, or perhaps because they do not think that is a public health necessity. From the perspective of public health institutions, however, high vaccination uptakes are needed as to achieve tangible population results. Indeed, from an epidemiological point of view, it would have little sense if very few people vaccinated. Differently from clinical medicine, where an intervention is successful when it brings about the desired result in the individual patient, public health measures are successful when the interventions bring about a decrease in the incidence of the relevant pathology they are directed to. In the same way, while an individual's health can be said to have benefited from a medical intervention when she has been healed from a certain condition, population health can be said ameliorated in a purely aggregative sense: when life expectancy increases on average, when infant mortality and death rates decrease, when the quality of life of indigent patients improves or, again in our case, when the incidence of disease falls down.

In order to achieve high-uptake, hence, the policy means that may prove more effective are not necessarily those that would also ensure maximum respect of individuals' liberties, at least in a non-interference sense.

How to balance hence autonomous choice and the population oriented duty of beneficence that public health institutions have?

As we saw in the brief historical reconstruction of immunization policies, state endorsed campaigns have the advantage of being able to offer the opportunity of vaccination to all, no matter their social background. They can do so,

however, by somewhat limiting absolute freedom of choice for the individual. Clearly, this limitation can come in different forms. It may imply a state mandate or softer forms of coercion. For instance parents can be granted the final choice, but they can be required to consider vaccination and be informed about its benefits (Dare, 1998). Sometimes, like in the US, schools admittance may be conditioned on immunization. This policy has proven highly efficient at the cost, however, of limiting a little bit individuals' freedoms. As for the case study of this work, moreover, issues of social justice come back again in that an unequal epidemiological burden of HPV-related morbidities exists between different socioeconomic groups.

The question to be asked as to the ethical trade-off hence is: is it right to diminish, in some way, individuals' choice for ensure equal distribution and reducing disparities in vaccine uptakes? And if it is so, up to what extent?

Finally the third trade-off pertains to a specific policy question in the HPV context. As I have shown, HPV is a sexually transmitted virus. Although the most burdensome effects of HPV infections are on women, men are still vectors of the infection. An issue of gender equity hence arises as to whether it is fair that only girls carry the burden of prevention and vaccination. Moreover, epidemiological studies are ascertaining that, although less frequently, HPV-related cancers affect men too. This consideration would suggest that there are reasons for vaccinating also men. As some studies show, however, vaccinating also men may not be cost-effective. Therefore, issues of gender equity - if considered valuable - should be traded-off against other important efficiency concerns. The ethical issue thus become: should society spend more for fostering and preserving equality among sexes?

These questions will inform the remaining part of this work. In particular, in the following chapter I will assess how present policies accommodates the first two trade-offs and how they try to put them in balance together with all the other morally relevant interests. By the end of that chapter I will be able to tell what are the advantages and disadvantages of each policy scheme, and whether there is one that is able to achieve a better equilibrium. In the fifth chapter, instead, I will tackle the third trade-off. In the sixth chapter I recollect the problems faced and provide a further layer of analysis as to their solution. In each chapter, however, I will take a normative stance as to the specific questions that arise in that context. The morally grounded interests here illustrated and the theoretical tools in the first chapter of this work will, at several points, emerge in the discussion sometimes clarifying and some other radicalizing the issues at stake.

Chapter four. HPV vaccination programmes: a normative comparative analysis

1. Introduction

In the previous chapters I have introduced HPV vaccination, I have analysed its promises as well as the morally sensitive issues that this intervention brings about. By the end of the chapter, I have also specified what are the morally grounded interests at play within this intervention. I said that all these morally grounded interests only hold prima facie. That is, they can be overridden in certain circumstances. The beneficence model of public health ethics presented in the first chapter, more specifically, indicates what are those conditions that can justifiably override, for instance, concerns for individual liberty. The analysis put forward in the second chapter, moreover, has shown that public health activities are justified also from the perspective of justice in that they provide fair equality of opportunity. By an exploration of the social determinants of health and health inequalities I have specified a further requirement of justice for public health activities. Although some inequalities may be permitted also in the Rawlsian framework, I have shown that public health policies should strive to avoid worsening existing health inequalities. Also in this case a caveat is in order. A policy that correctly addresses the problem of existing inequalities and puts in place all the necessary means as to avoid an increment of them acts justly. This means that if inequalities should persist after the intervention has been put in place, the latter would be unfortunate but not necessarily unjust.

Having further clarified these points, let us now proceed to the comparative analysis of the different policies devised for HPV control and the reduction of cervical cancer cases. I am interested in understanding how the different policies fare with respect to the interests I have shown to be in place in this context. My final aim is to understand whether there is a policy model that best harmonizes all the morally relevant interests at stake. Three policy models seem to emerge so far for tackling HPV as a public health problem. The first are those policies that mandate vaccination. These policy models have been enacted in some states of the US, and they are still waiting for approval in others. In these states vaccination is obligatory for girls before admittance to the sixth grade. The second model, instead, leaves HPV immunization to the private initiative of individuals. The voluntary model is adopted in the vast majority of countries that have decided to take action against HPV. The voluntary model, however, is a heterogeneous one and deserves further specification. I will identify three of them. In the first, public health authorities recommend the vaccine, but its administration is left to the decision of the parents and their paediatricians. This model is the most widespread in the US, and I will thus take them as representative of this mode of intervention. The second voluntary model, moreover, is one where although the final decision as to whether vaccinate is left to individual choice, the state nonetheless actively proposes the vaccine free of charge to everyone and by an invitation letter. I will take Italy as an exemplification of this way of intervening. Finally, the third voluntary model offers vaccination free of charge and delivers it through schools. I will call this third scheme the school-based model. It is adopted in the UK and in Australia and, for the sake of simplicity, I will take the former as an example. As mentioned, my goal is to define by the end of this chapter whether or not there

is a model that better balances all the morally relevant interests I have identified before. Nonetheless, I will also assess each model in its own merits and show its advantages and disadvantages. To proceed in an orderly fashion I will organize my discussion around two problematic themes. The first theme I identify is the problem of justification. Under the problem of justification, I will assess whether each policy is able to justify its means of intervention. Clearly, the more intrusive the means the more general and powerful the justification should be. In this context the tools of the beneficence model previously introduced would prove useful. The second theme I will discuss is the problem of justice. I would ask whether the benefits and burdens of the intervention are fairly distributed across society. In the second chapter I have shown that public health interventions are generally justified from the perspective of justice because they sustain fair equality of opportunity. As explained in that chapter, moreover, I will see whether the different policies are able to meet the requirement of the negative aim of justice. That is, I will see whether each policy is acting in a context in which health inequalities exist, and whether the mode of intervention runs the risk of worsening them.

2. HPV and public policy

Before proceeding with the ethical analysis, however, it is important to see more in detail what are the policy actions taken so far for HPV control in the different countries that will be part of my analysis. The WHO has supported policy efforts to implement mass vaccination programmes and issued, in 2009, a position paper that, although not binding for member states, is supposed to guide their policy actions. The WHO position on HPV states:

Who recognizes the importance of cervical cancer and other HPV-related diseases as global public health problems and recommends that routine HPV vaccination should be included in national immunization programmes. […] HPV vaccines are most efficacious in females who are naïve to vaccine-related HPV types; therefore, the primary target population should be selected based on data on age of initiation of sexual activity and the feasibility of reaching young adolescent girls through schools, health-care facilities or community-based settings. The primary target population is likely to be girls within the age range of 9 or 10 years through to 13 years (World Health Organization 2009, 128)

Most countries in the developed world, however, took policy action slightly before the WHO took an official position on the matter. Let us explore those that will be part of my analysis.

HPV policies in the United States. Vaccination policies in the US generally take steps from the recommendation issued by the *Advisory Committee on Immunization Practices* (ACIP). As we read in its website[22], ACIP is a group of experts in immunization appointed by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary and the *Centers for Disease Control and Prevention* (CDC) on the control of vaccine-preventable diseases.

ACIP provides advice to the federal government on vaccines related issues through written recommendations for the routine administration of vaccines to children and adults in the civilian population. Private insurers and the federal government to determine what vaccines they will cover generally use the recommendations of ACIP. Vaccines recommended by ACIP are included in the

[22] http://www.cdc.gov/vaccines/recs/acip/. Last access: November 20th, 2011.

Vaccine for Children Program (VFC), a federal program that provides vaccine for free to children who are uninsured or who lack the resources for affording vaccines. Moreover, member states generally use ACIP vaccine recommendations to mandate immunization before entrance in public schools. The ACIP recommended HPV entered the routine immunization schedule in March of 2007. In particular, it recommended Gardasil to be administered to 11-12 females and to females aged 13-26 in a catch up programme (Markowitz et al. 2007). Later on, in 2010, ACIP also recommended Cervarix for the same age group (CDC 2010), and very recently, on October 25th 2011, extended the recommendation to boys in the same age group (ACIP, Resolution No. 010/11-1)[23].

ACIP is a federal advisory board and when it issues its guidelines, physicians are asked to follow them and propose the vaccine to their patients. In this case, vaccination is left to the private initiative of physicians and parents alone. Since then, however, several states have proposed legislations to push uptake in a more centralized manner. So far, 41 states have introduced legislation related to HPV vaccines. Of these, 24 (Kentucky, New York, Texas, New Mexico, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Illinois, Kansas, Maryland, Massachusetts, Michigan, Missouri, Minnesota, Mississippi, Ohio, Oklahoma, South Carolina, Vermont, Virginia West Virginia) have introduced legislation that would require proof of HPV immunization for girls before enrolment to the sixth grade. Virginia and the District of Columbia are, however, the only two that have actually enacted school mandates. In all other

[23] This recommendation is very recent and has not yet been published in the *Morbidity and Mortality Weekly Report,* the 'official voice' of CDC. This means, that the recommendation is still not official. Nevertheless, CDC generally receives ACIP recommendations.

cases the decisions are still pending. Not all states are considering mandates. Some of them, instead, have approved laws to educate the public (North Carolina, North Dakota, Missouri, Rhode Island, Utah), to distribute free vaccines (New Hampshire, South Dakota, Washington), or to require to insurance schemes to cover the vaccine price (California, Rhode Island, South Dakota) (source: National Conference of State Legislatures)[24].

HPV policy in Italy. Italy provides a universalistic health service to all its citizens. It is funded through the tax system and access is guaranteed according to need and not ability to pay. The Italian *Servizio Sanitario Nazionale* (SSN - *National Health Service*) decides what are called the *Livelli Essenziali di Assistenza* (LEA – Minimal Levels of Assistance), that is, what are the minimal services provided. The objectives of the SSN are decided in an agreement between the *Ministero della Salute* (Ministry of Health) and the twenty regions in what is called the *Conferenza Permanente Stato-Regioni* (CPSR). The implementation of the objectives, moreover, is left to the regions that provide the service through a number of local health units called *Aziende Sanitarie Locali*. The SSN includes in the LEA a number of childhood vaccinations. Among them, four (tetanus, polio, HiB, diphtheria) are obligatory and the others only recommended. All of them are offered free of charge. Also with regards to vaccinations the objectives are decided at the national level by the CPSR, that issues every three years what is called the *Piano Nazionale Vaccinazioni* (PNV – National Vaccination Plan), and their implementation is left to the 20 regions (Ministero della Salute 2010). On December 20th 2007, the CPSR agreed to include HPV vaccination in the PNV. The target group of the vaccination are 11-12 year-old girls to whom the

[24] Web page: http://www.ncsl.org/default.aspx?tabid=14381 (Last access: October 30, 2011)

vaccine is offered free of charge. In the agreement we can read that the choice of the target group was driven by the following considerations (Ministero della Salute - Conferenza Permanente Stato Regioni 2007):

- the vaccine works best before the onset of sexual activity
- the communication with families is facilitated
- to maintain the vaccination offer within the established network of expertise in vaccination
- to limit inequalities

The families are informed of the HPV vaccine offer by an invitation letter sent to them by local health units. The letter describes the link between HPV and cervical cancer, known duration of the vaccine-induced immunity, and the fact that immunization only confers protection against two high-risk HPV viral types. In the letter, moreover, families are informed that it will be anyway necessary attending cervical cancer screenings in the future. Parents who decide to adhere to the offer are then asked to contact their paediatrician or their local health unit. As we read in the PNV for the years 2010-2012, the national objective of the policy is to reach 95% of the target population by 2015 (Ministero della Salute 2010).

HPV policy in UK. The Italian SSN is directly inspired to the UK *National Health Service* (NHS). Also the NHS indeed provides universal access to medical and preventive services to all citizens free at the point of use. The NHS is publicly funded through the taxation system. Each of the UK countries (England, Scotland, Wales and Northern Ireland) has it own NHS that is accountable to the respective government. Like in the US, vaccination policies in the UK take step

from the recommendation of an advisory board of experts called *Joint Committee on Vaccination and Immunization* (JCVI). As stated in its website, JCVI' terms of reference are: "To advise the Secretary of State for Health and Welsh Ministers on matters relating to the provision of vaccination and immunisation services, being facilities for the prevention of illness"[25]. Upon request of the Secretary of State, the JCVI makes recommendation for the introduction of new vaccines based on an assessment of their public health impact, safety, efficacy and cost effectiveness. The committee may also make recommendations to the ministries of Scotland and Northern Ireland. The JCVI introduced the HPV vaccine in the UK in September 2008 and recommended targeting the programme at girls aged 12 and 13, with a catch up campaign for girls aged up to 18 to be carried out over a three-year time frame. To maximise uptake and public health impact, the JCVI decided to deliver the three-dose schedule through schools as part of the publicly funded NHS. In the recommendation statement the JCVI underscores the importance of communicating to women that cervical cancer screening remains an essential component of the cancer prevention programme. The JCVI, moreover, chose to administer the bivalent vaccine (Cervarix) due to its more competitive cost (Departmen of Health, Joint Committee on Vaccination and Immunization 2008).

As with all JCVI recommended immunizations in UK, the HPV vaccine is offered free of charge and on a voluntary based. Schools, which receive information material from the *Department of Health*, inform parents of the opportunity through school nurses who, after receiving consent, also administer the vaccine.

[25] http://www.dh.gov.uk/ab/JCVI/index.htm (Last access October, 30 2011).

3. The mandatory model

Using the tools of the administrative state to require vaccination compliance is an option now discontinued in many countries. For instance, in Europe only Belgium, Poland, Greece, Spain and Italy have still in place compulsory policies for some vaccinations. In cases like Italy, moreover, the decision as to whether continuing with these policies is now left to single regions and two of them, Piedmont and Veneto, have already made all vaccinations voluntary (Moran, Gainotti, and Petrini 2008). Among the industrialized countries, also the US require some vaccinations by law, conditioning school entrance upon immunization.

Let us see, however, whether the compulsory model is appropriate for the HPV case, and how if fares with respect to the morally grounded interests previously identified. The compulsory model is certainly attractive from the perspective of the population health interests. Arguably, mandating HPV vaccination would ensure widespread compliance, and reach the population target quite easily. Although HPV vaccines do not target all the oncogenic types, it is still required that a certain number of people in the target group get actually vaccinated in order to observe a sensible reduction of HPV related morbidities. In the case of HPV vaccination this number is calculated around 75-80% (Garnett 2005), if only girls are to be vaccinated. Ideally, should the vaccination reach everyone all the HPV 16 and 18 cervical cancers would disappear thus drastically

changing the epidemiological profile of the disease[26]. In other words, if immunization is not widespread its potential public health benefit gets lost, and the intervention then becomes a drug for individual risk reduction only (Aronowitz 2010). Clearly, this may not be a problem as such, it may be so, however, when public efforts and funds are put in order to achieve population health goals. The use of mandates proves attractive not only from an epidemiological point of view, but also if we consider issues about equity and justice. These concerns, indeed, are especially relevant in the light of the disproportionate epidemiological burden of cervical cancer in the US (the only country in which mandates are proposed) in women belonging to economically disadvantaged groups, who are also less likely to receive PAP smears and follow-up care after abnormal results (J. S. Smith 2008; Cuzick et al. 2000).

Mandates fare well with respect to justice and population interests but less in terms of respect for the autonomous choice of individuals. Respect for autonomy is of pivotal importance in liberal societies, and even more in contexts so delicate as decisions regarding healthcare. In the context of HPV mandates, hence, a trade-off between individual choice and population interests exists. It is important then to see whether it can be resolved. In this context, resolution requires the exploration of the reasons that may justify the use of compulsory means and whether they hold.

As I have illustrated at several points throughout this work, one of the most general justification for restricting liberty is the appeal to John Stuart Mill harm principle. Does HPV warrant the use of the harm principle? Some has claimed it

[26] As we will see below (*infra* chapter 5) the issue is more complicated than that. Achieving herd effects will most likely require including males into the programmes. The point to bear in mind here is that for population health goals to be observed is required that a high number of people gets immunized.

does (Balog 2009), in that the vaccine would protect also the spread of infections to third parties. This argument, however, needs to be spelled out more precisely since, as it stands, appears to be not decisive. What we need to understand, accordingly, is both who are the actors whose liberty is restricted and who are the third parties that could be harmed. On a first reading, the actors whose liberty is restricted are the receivers of the intervention themselves. In the HPV case, however, this justificatory track cannot be followed in that girls are more the victims of the infection rather than the vectors. An appeal to the harm principle, hence, would only be possible if compulsory policies were adopted on a gender-neutral base. I will dwell more extensively with issues related to gender fairness in the following chapter, so let us see what are the other alternatives for justifying compulsory policies by the means of the harm principle.

The second, and most plausible, option is to conceive of girls as the third party that would be harmed should vaccination not be provided to them. In this reading, the liberty restricted is that of parents on the presumption that state mandates better protect girls from ensuing harm. States, in general, grant broad space for parental autonomy with regards to the protection of their children's interests and only rarely intervene on those matters. Heather Harrell notes that in the context of food choice and consumption the state regulates infrequently to curtail parental choice, and does it only in specific public circumstances. For instance, states do regulate what kind of food is offered in public school cafeterias. Nevertheless, she argues, the regulated behaviour is occurring outside the home and the state functions as the parent in a school setting. It is only in extreme situations that the parental right is limited based on the health

risks that result from the child's diet (Harrell 2009, 136). Is, in the HPV case, the magnitude of harm girls are exposed to so vast as to justify state intervention? Some parents could argue, on their side, that they are not harming their daughters if they do not allow them to be immunized in that different other methods exist to avoid HPV infection or to control it appropriately. For instance, they could say that they will teach their daughters how to conduct a responsible sexual life and the kind of protection needed to avoid all sexually transmitted infections. This kind of reasoning need not to be expressed in religious terms, for instance some parents may very well prefer not to let their daughters run the even small risks that can ensue from vaccination. Some words of cautions are, however, in order. Several studies show that although condom use reduces the risk of contracting a HPV infection they do not eliminate it. In fact, HPV transmission to occur does not need a full penetrative sexual intercourse; a skin-to-skin genital contact appears sufficient. Thus condom use only partially protect from the infection (Manhart and Koutsky 2002; Vaccarella et al. 2006; Winer et al. 2006). This fact notwithstanding, supporters of parental autonomy can claim that even admitted that the risk of infection may still be present, their educational tools would be enough to avoid serious harm to their daughters. They can, for instance, provide full education to their daughters as to how correctly prevent cervical cancer. A conscientious mother, for instance, can educate her daughter to regularly attend cervical cancer screening so drastically reducing her risk to get the disease. From some parents' perspective, hence, the risk of harm imposed to their daughters is neither certain (there are other ways to protect oneself), nor immediate (even if one gets infected there are other preventive strategies to avoid the disease). The reasons to justify HPV

mandates on the grounds of the harm principle seems thus to be weakly supported.

So far, we have seen that an appeal to the harm principle does not, by itself, provide a justification for mandatory HPV vaccination programmes. It does not so because we cannot identify a genuinely other-regarding harmful action that individuals whose liberty is restricted are performing. We cannot do that neither if we consider girls the subjects of the restriction, nor if we consider their parents. Let us thus explore another option. As someone suggests, gender-based vaccination programmes can be considered interventions that target behaviour (Harrell 2009) – i.e. sexual activity – for the harmful consequences it may bring about to the agent herself. In moral and political philosophy, the act of benefiting someone against his or her expresses wishes is called paternalism. Although weaker, the appeal to paternalism is sometimes considered ethically justified by some scholars (Childress et al. 2002; Beauchamp and Childress 2009). This argument has been briefly touched upon by some authors in the context of HPV vaccination, but not properly spelled out (Malmqvist et al. 2011). Let us then see whether an appeal to paternalism can be ethically justified in the HPV case.

Paternalistic actions are commonly divided into two groups: hard paternalistic interventions and soft paternalistic interventions. Hard paternalism occurs when the harmful action curtailed is voluntary and self-regarding. Soft paternalism, instead, refers to those actions that while self-regarding are not voluntary. Some authors argue that soft paternalistic interventions are hardly unjustifiable, and what is ethically problematic is the use of hard paternalistic means (Childress et al. 2002). The classical examples of hard paternalism are

seat-belt legislations. We know that the use of seatbelts reduces the risk of harmful consequences for the driver in case of a road accident. Clearly, from the individual perspective, not wearing the seat-belt does not put anyone at risk if not the agent that so decides. Is it morally problematic to mandate their use? One first line of argument would consider these laws morally dubious in that they are disrespecting the autonomous choices of competent individuals. Another line, instead, would not consider these laws paternalistic at all and would appeal to the financial costs that road fatalities bring about in terms of increased hospitalization and long-term care, or the emotional costs to observers and rescue squads. For the purposes of this work I do not want to dwell on the debate as to whether seat-belts laws are cases of hard paternalism or not. Instead, what I want to underscore is that even if we granted that these laws are an expression of hard paternalism, they can be nonetheless justified from a public health perspective. It is so, I propose, in that they do not threaten individuals' core values while protecting them against serious risks.

Having this example been made, it remains to ask whether HPV vaccination is a case of hard or strong paternalism. In one sense, it may be interpreted as a kind of soft paternalism. Indeed, although sex is in general a voluntary act one may lack sometimes the capacity to be fully protected against all risks. For instance, one can imagine of cases of sexual assault in which the victim gets infected with HPV against her will; one can also imagine of a woman in a long-term monogamous relationship that is, nonetheless, at risk because of her unfaithful husband; or one can also appeal to the fact that the use of condoms does not eliminate the risk of infection. An argument for soft justifiable paternalism would thus be that the agent is not able to protect herself properly and that thus

she is unknowingly at risk of harm. Although I can agree that the intervention resembles a kind of soft paternalism, I would resist the temptation to consider it an ethically justifiable one. It is so for the reasons that let me instead justify hard paternalistic laws on seatbelts. While in the previous case we were not observing any core value to which freedom from seatbelts may be attached, in the HPV case the regulation would enter into one of the most private areas of many individuals' lives. Moreover, if we acknowledge that the magnitude of harm one is at risk of drops exponentially when one takes due precautions and performs screening regularly, the appeal to a justified form of paternalism looks even less attractive. If we add to this consideration the fact that, although rarely, vaccines may give rise to adverse events, and that the duration of HPV vaccine-induced immunity is still not clear, we can say that there are reasons for respecting those who choose to tackle HPV-related risks differently.

So far I have shown the ethically problematic issues as to what pertains compulsion with regards to HPV policies. In particular, I have shown that there are good reasons for respecting the morally grounded interests of parents. As to the positive aspect of mandates, however, it needs to be mentioned that they would fairly distribute the benefits and burdens of the intervention to all the socioeconomic strata. In contexts like the US, where a disproportionate burden of cervical cancers is observed in the disadvantaged strata of society, this aspect may function as a justification for the use of mandates. Clearly, other means can be adopted, besides mandates as to achieve this goal. In the next section I will mention some of them that are able to both meet the interests of economically disadvantaged groups by making the intervention accessible as well as preserving the morally reasonable interests in parental autonomy. For the

moment it suffices to say that considerations of justice are those that more forcefully support the use of state mandates.

As said in the sections presenting HPV vaccination policies, mandates are used only in some states of the US. In particular, of the 24 states that have introduced bills as to require vaccination to girls upon entrance to the sixth grade, only Virginia (October 1, 2008 – Senate Bill 1230) and the District of Columbia (January 1, 2009 – Bill 17-0030) have enacted legislation. A look at those bills may be useful to understand how current mandatory policies try to balance interests to privacy with population goals in practice. Both states, indeed, grant broad exemption clauses to parents. In the District of Columbia's bill B 17-30 we can read: " The parent or legal guardian, at his or her discretion, has elected to opt out of the HPV vaccination program, for any reason, by signing a form prepared by the Department of Health that states that the parent or legal guardian has been informed on the HPV vaccination requirement and has elected not to participate" (District of Columbia 2007, § 5). Similarly, in the Virginia law parents are granted the right to opt-out. As we read: "After having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board, a parent or guardian may elect, on an appropriate form prescribed by the Board, for his child not to receive the human papillomavirus vaccine" (Virginia Acts of Assembly 2008, §32.1–46 D3). The possibility of exemption weakens the force of those arguments based on parental autonomy, but only up to a certain point. For instance, some differences can be noted between the two ways of conceiving the exemption clause. In the District of Columbia's case, the opt-out is granted but only limited education is provided to the parents. The parents are indeed

informed only about the existence of the requirement, but not about the link between HPV and cervical cancer. Vaccination is thus presented, primarily, as a duty from which one can opt-out if she so wishes. Instead, in the case of Virginia, we can more properly speak about an informed refusal. In this sense, where mandates are accompanied by educational tools to increase awareness of the risks connected with HPV the concerns for parental autonomy looks less powerful. Moreover, broad exemption clauses are present in most introduced legislations, but not in all. For instance, legislation introduced in West Virginia and Connecticut would grant exemptions - should mandates will be approved - only for medical reasons; in some (Georgia, Massachusetts, Missouri, and North Carolina) for medical and religious reasons; in all the other states, instead, exemptions would be granted for any reason (National Conference of State Legislatures)[27]. If we take into account this diversity we can speculate that a problem of fairness would be put in place should strict exemption clauses be allowed. In fact, one may ask whether it is right that some may exempt and others not. As I have shown above, indeed, reasons for not vaccinating girls may be equally justified from a non-religious perspective. That is, some parents may put forward sound arguments as to non-vaccinate their daughters without any specific religious motivation behind. Reasons for allowing vaccination exemptions to some groups only have been generally supported by the need to maintain herd immunity - thus reducing the likelihood of epidemic outbreaks - and to respect religious minorities that reject vaccination *tout court.* Some states, moreover, confident of the widespread acceptance of vaccination as a social practice, have broadened the scope of exemptions as to include people

[27] Web page: http://www.ncsl.org/default.aspx?tabid=14381 (Last access: October 30, 2011)

with mundane reasons for rejection. In the case of HPV, however, there is no herd immunity to be protected yet, nor is it clear whether it will be one of the objectives in the near future. In absence of a precise commitment to the elimination of virus circulation thus, limiting the possibility of exemptions to some appears to be unjustified.

As to what pertains the political context of the US, even when mandates include broad exemption clauses, as in the two cases just described, a general antipathy towards governmental coercion, may cause a public backlash in terms of reducing trust towards vaccination policies in general (Gostin and DeAngelis 2007; Javitt, Berkowitz, and Gostin 2008; Colgrove, Abiola, and Mello 2010). In terms of my analysis, hence, the use of mandates can give rise to the paradoxical effect of running contrary to population health interests in the long run. Clearly, the 'public backlash' argument is not supported by evidence, and as such it is not conclusive. What these authors have in mind, however, is the idea of the 'least coercive alternative' as an ethically preferable option for public health policies. To recall, the latter is an injunction for public health policy to prefer interventions that are not only effective but also the less intrusive as possible. It remains hence to see how the other, less intrusive, options perform. Before passing to the analysis of the other options, however, it is worth summing up the results of this section.

On the positive side, state mandates would ensure high uptakes and, as a consequence, would fairly distribute the benefits and the burdens of the intervention to all. In this respect, population health and justice would be well served. On the negative side instead, they appear to be weakly justifiable by an appeal to either the harm principle or ethically justifiable paternalism unless

vaccination is made mandatory for both genders. In this regard, they do not take sufficiently into account autonomy-based interests. Having explored both the advantages and disadvantages of the mandatory model, let us now explore whether other models provide a better balance of the moral concerns at play in the HPV vaccination context.

4. The voluntary model

In the previous section I have shown what are the morally sensitive issues in the context of mandatory models. I have argued that while they are attractive from the perspective of justice and with respect to the population benefit they can bring about, they fall short of providing strong moral justifications for the means adopted. The fact that mandatory policies do not correctly address concerns for individual choice, however, does not imply, by itself, that they are not justifiable. If, for instance, we would be able to show that no less restrictive alternative is able to reach comparable results, then we would have reasons to consider the mandatory model promising. For instance, we may find that voluntary models fare too badly in addressing other important moral concerns and thus, on balance, they may look less attractive. To understand whether this is the case, I will now investigate more deeply what voluntary models have to offer. It is important to recall that I am here interested in those voluntary models in which, nonetheless, there is some kind of state action involved. My primary interest, indeed, is to scrutinize what are the ethical implications of HPV vaccination once states or governments decide to take specific public health policy action, and not to advocate for HPV vaccination programmes. The fact that in some contexts no policy action is taken with regards to HPV may be regrettable, but the job of showing why it is so is better left to public health

advocates. Having these clarifications been made let us now proceed with the elucidation of the advantages and disadvantages of the voluntary models. I will first outline those aspects in general terms. I will then discuss in some detail the different ways in which voluntary models have been implemented in different contexts.

Voluntary models are certainly attractive from the perspective of parental autonomy. They do not force vaccination but only propose it. The idea behind these models is the potential overlap between private and public interests. That is, the realization that the public interest in reducing the number of cervical cancers can coincide with the private interest some women have in being protected by such a disease. The public interest in preventing cervical cancer is two-fold. The first is a general moral motivation we have in promoting welfare and avoiding morbidities and premature deaths. Following mainstream bioethics and public health ethics, in the previous chapters I have identified this moral motivation as an obligation of beneficence. The second refers, more pragmatically, to the benefits that vaccination would bring about in terms of a prospective reduction of costs for the treatment of these morbidities. Several studies in health economics show that HPV vaccination, should it achieve a coverage of about 75-80% of the female population, would be a cost-effective strategy. That is, the up-front expenditure for vaccination would be entirely offset by costs averted through diseases prevention. This seems to be so, at least, in those countries that I will be concerned about, that is the US (Newall et al. 2007; Kim and Goldie 2008; Chesson 2011), UK (Kulasingam et al. 2008), and Italy (Mennini, Costa, et al. 2009). The public interest, hence, is not only that of reducing the number of illnesses, but of doing that in a way that is cost-saving.

In other words, part of the public interest consists in involving in these programmes as many individuals as possible.

Women's private interest in preventing cervical is also multifaceted. Cervical cancer indeed affects women in a two-fold manner. First, as I have shown above, cervical cancer is one of the most common in women aged 15-44, that is in an age in which they are still working and raising a family. Second, cervical cancer affects women in their reproductive system, and almost certainly many women have a fundamental moral stake in reproduction as an important part of their biography. To let the overlap of interests emerge, the state may put in place a series of incentives, and the offer of the vaccine free of charge is one of them. In cases in which this occurs, voluntary models seemingly score well also from the perspective of justice. In fact, when financial incentives are in place, the vaccination offer is not limited to the affluent strata of society but open, at least formally, to everyone. In the sense developed in the theoretical part of this work, these kinds of interventions serve to foster fair equality of opportunity as a protection of a normal opportunity range for all.

However, voluntary models also have problems. For instance, if the incentive system is not effective they may serve population health goals inadequately. These problems may bring about an odd distribution of the benefits of the intervention, with only the most affluent and cultivated strata of the society taking advantage of the offer. In contexts in which a disparity in the epidemiological burden of cervical cancer between the richest and poorest exists, voluntary policies may worsen existing inequalities thus failing to serve the negative aim of justice. To understand whether this is the case is necessary to assess whether in the contexts in which HPV vaccination intervenes

inequalities are present. For the purposes of this work I restrict my attention to health inequalities with regards to cancer, where available, and cervical cancer in particular. I will moreover indicate the extent to which these inequalities are present in each country object of this analysis.

4.1 The voluntary model in the US

The moral advantages of the voluntary models in general terms are also present in the policies object of my comparison. As anticipated in the presentation of the policies, the US federal government *de facto* recommends the vaccine through the ACIP. When no specific legislature is introduced by single states, however, vaccine administration is left to the private initiatives of paediatrician proposing it to families that, in turn, can accept it or not. Arguably, in this context paediatrician will have to follow the ethical standard of informed consent. That is, while proposing it they have to explain the benefits and the risks connected to intervention, and then evaluate whether the receivers of the intervention understand the information and voluntary consent to the procedure. In this sense, it seems plausible to say that parental interests in making truly autonomous choices are respected. When ACIP recommends a vaccine, moreover, it then enters the VCFP, thus covering the costs for uninsured children. In this sense, the possibility of getting the vaccine is open to all. Whether this is sufficient from the perspective of justice remains to be seen. To the exploration of this point I now turn.

Cancer related inequalities exist in the US along two axes. The first axis refers to disparities of cancer rates and mortality according to race and ethnicity. The second, instead, refers to disparities with regards to socioeconomic status. These axes operate in a concomitant manner both in the general case and with

regards to cervical cancer in particular. It is thus worth exploring them. I will first give a sketch of the problem as it is present with cancer at all sites, and then proceed with the cervical cancer case. Cancer registries in the US show that African Americans have the highest death rate from all cancers combined and from specific sites (lung, colon, female breast, prostate, and cervix) of all the other ethnic groups in the same country. Moreover, the death rate from cancer among African American males is estimated to be 1.4 times higher than that among White males; for African American females, instead, the rate is 1.2 higher. From the inception of the 'war on cancer' until the 1990s the disparity in death rates between these two groups widened. Although this gap eventually narrowed, it still remains larger than it was in the 1970s (Ward et al. 2004; Byers 2010). Similar trends of increased disparities between the 1970s and the 1990s can be observed also with respect to county poverty level. The death rate from all cancer sites in the 1970s was 2% higher among men in poorer counties compared with more affluent counties; by the end of the 1990s it increased to 13%. Among women, instead, the death rate from all cancers combined was 3% lower in poorer compared with more affluent counties in the 1970s; by the end of the 1990s it was 3% higher (Ward et al. 2004).

These trends are also observed with specific regards to cervical cancer. While declines in incidence and mortality rates have been observed since the 1970s - thanks to the wide-scale implementation of PAP screening - across all groups, marked disparities still exist. As reported by the Surveillance Epidemiology End Results database (years 2000-2008), Hispanic women are diagnosed with cervical cancer almost 1.9 times as often, and African women 1.5 times as often,

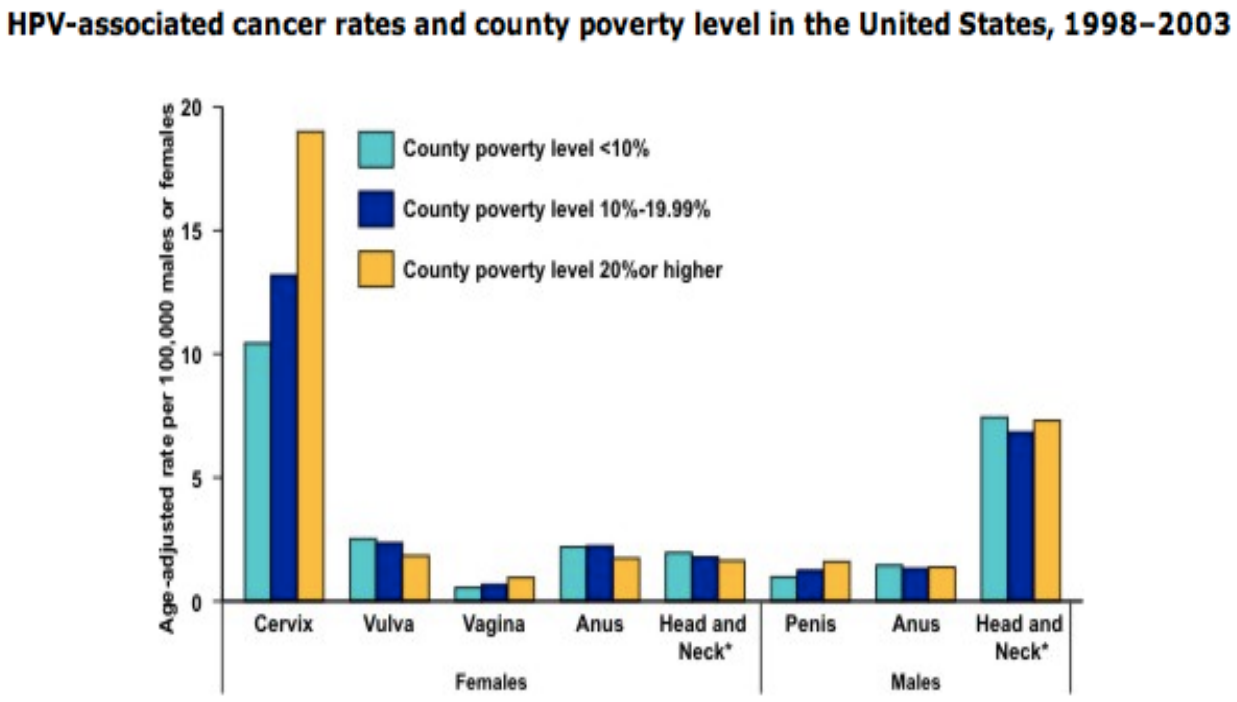
than non-Hispanic white women (Howlader et al. 2011)[28]. Differences exist regarding the stage of cancer at diagnosis among the various groups, with white women more likely to be diagnosed the earliest (Downs et al. 2008). Speaking of disparities with regards to ethnic and racial groups, however, does not give a full account of how cervical cancer clusters with relation to a multidimensional pattern of determinants. A study conducted between 2000 and 2004 among 48 states of the US (Du et al. 2010) shows a clustering of cervical cancer mortality in those areas where it is observed: a high proportion of black population, low socioeconomic status, low PAP test rate, low healthcare coverage. The major relevance of the socioeconomic determinant, rather than ethnicity only, is observed in the Appalachian area where cervical cancer mortality rates cluster only with high poverty rate, low education level, and limited access to healthcare resources. A further illustration of this fact can be given via the aid of the table below. The table – based on a study done on California's cancer registries (Yin et al. 2010) – shows a gradient in the incidence of cervical cancer operating almost consistently through the whole socioeconomic spectrum. As we can observe the incidence is highest in those groups with the lowest socioeconomic status and it decreases, step by step, until it reaches the minimum in those groups at the highest level of the socioeconomic ladder.

[28] The Surveillance Epidemiology End Results of the National Cancer Institut provides US related cancer statistics in form of reports and a web-based serchable tool. The latter can be found at: http://seer.cancer.gov/csr/1975_2008/browse_csr.php Last access: November 15th, 2011.

Cancer site	Socioeconomic status level	Incidence x 100,000			
		Non Hispanic White	Black	Hispanic	Asian Pacific Islander
Cervical cancer	1 (lowest)	15.0	14.9	20.9	15.1
	2	10.9	10.1	16.2	10.8
	3	8.4	8.7	13.5	9.8
	4	6.8	6.0	12.1	8.3
	5 (highest)	5.5	8.1	10.3	7.1

Table 2: Socioeconomic and ethnic gradient in the incidence of cervical cancer in the US. Adapted from (Yin et al. 2010)

The inequalities so far presented precede the initiation of HPV vaccination programmes. Whatever one thinks about the justice of present inequalities, however, a question remains as to how the vaccine will impact on them. I identify three possible scenarios, and I illustrate them with visual aid of the diagram below. In the diagram we observe the incidence of HPV-associated cancer in the prevaccination era. As we see, the incidence of cervical cancer – the only cancer for which a preventive strategy existed before vaccine introduction – in the most deprived areas (column in yellow) is almost twice as that in the richest areas (dark blue and light blue columns). If we move to observe the incidence of HPV-associated at other cancer sites – those for which there is no alternative strategy other than the vaccine – nearly no inequality is observed.



Graph 1: from *The Centers for Disease Control and* Prevention's website: http://www.cdc.gov/cancer/hpv/statistics/poverty.htm

In the first scenario, more people in the light blue column take advantage of the vaccine than people in the blue column that, in turn, take advantage of it more than people in the yellow column. In this scenario, every group will improve its condition, but those in the light blue column would improve it more. As a result, every group is better than it used to be prior to the intervention, but inequalities are increased. In the second scenario, instead, more people in the yellow column take advantage of the intervention, resulting into a flattening of the inequalities. In the third scenario, finally, all groups take advantage of the vaccine equally. As a result, perhaps, the height of all the three columns would go down in a similar manner. Which scenario is preferable from a justice perspective? Let us consider them one by one.

In the first scenario, every group is better-off after the intervention but the richest have benefited the most from it. This situation seems to contradict

Rawls' claim that the difference principle – i.e. inequalities are permitted when they are to the most advantage of the worse off – should not be intended as a trickle down principle, but it demands instead a maximal flow of benefits to the worse-off (Rawls (1971) calls this maximal flow chain-connectedness). Moreover, this scenario would go against what I called the negative aim of justice. The negative aim of justice requires that those inequalities that are clustered in systematic patterns of disadvantage should not be worsened. As we saw, cervical cancer rates are highest among those groups that are the poorest, the least educated, and also belonging to racial and ethnic categories that, at least in the US context, have long been discriminated. The first scenario is thus not ideal from the perspective of justice. Let us see now whether there are similar problems with the other scenarios.

In the second, equality is increased and the vaccination has served the worse-off better than the other groups. Is this outcome desirable? I would propose that it depends on how it is achieved. For instance, one can think of this outcome arising only from the aggregate of completely voluntary choices of the people belonging to this group. In this case, I argue, although uptake would be unequal, the ensuing result would not be unjust. Nevertheless, this hypothesis is unrealistic in that we observe that poverty and education are correlated with less use of preventive services. Reasons for lack of access include: long waiting time at health clinics, lack of transportation, no family support, and lack of available child care (Downs et al. 2008). To suppose that this would be the case in the HPV context is a wishful thinking with little evidentiary basis. More likely, this result could be achieved by devising a two-tiered model for pushing vaccination among the high-risk groups. Targeted policies, however, are

problematic from an ethical perspective. A targeted programme, indeed, may give rise to a climate of stigma and disrespect by fostering invidious social views about which communities, and which women, get HPV and cervical cancer. This point was already noted in the early days of the HIV epidemics when targeted screening was proposed for interrupting virus transmission from mother to baby (Faden, Geller, and Powers 1991). As it turned out, those mothers were disproportionately poor women of colour already subjected to social stigma and discrimination and who frequently lacked strong social support and opportunities to lead self directing lives (Powers and Faden 2006, viii). Also the second scenario is ethically dubious if it implies a diversity of treatment among groups.

The third scenario, instead, is one in which everyone benefits equally from the intervention. Some inequalities in cancer outcomes may persist but I argue this would not result necessarily in an injustice. Otherwise stated, the HPV vaccination is intervening in a context in which inequalities are already present, perhaps they derive from past injustices or perhaps they do not. The causal route that led to existing inequalities is very difficult to assess, for sure we observe that an increased risk of cervical cancer exists among differently situated groups, and that this heightened risk is clustered with other dimensions of disadvantage that when compound also lead to decreased opportunities for people belonging to that groups. Deciding whether those inequalities need to be completely redressed is not easy task. For sure it may be desirable, but perhaps may contrast with other priorities that are peculiar of each social context. To address this point, however, is not part of my concerns, in this chapter. What matters for my case, at the moment, is to conclude that as

long as the negative aim of justice is served HPV policies cannot be blamed for being unfair. In other terms, the residual inequalities that may result after the vaccine is given equally to everyone may be unfortunate, but not necessarily unjust. The inequities of the distribution, in other words, would depend on other factors that determine the whole social arrangement.

The benefits of HPV vaccination programmes would be seen only in some decades from now. Cervical cancer takes long to develop after HPV infection, and the vaccination campaigns have just started. Some trends are, however, already observable. In the US, for instance, uptake in the target group is still low, around 32% (Vicari et al. 2011; Dorell et al. 2011). Some data are also available with regards to vaccine initiation with reference to state and county poverty level. One study, in particular, notes geographic disparity in HPV vaccination associated with area poverty, that is, states with a higher poverty level show less vaccination coverage than those observed in the richest areas (Pruitt and Schootman 2010). Other studies, instead, concentrate on the reasons that lead to a positive vaccination choice. For instance, it is noted that vaccine initiation depends on mothers' screening behaviour and previous experience with HPV infection or cervical cancer, and whether the family paediatrician has recommended it (Dempsey et al. 2006; Chao et al. 2010; Bartlett and Peterson 2011). This means, in other words, that the girls who are more likely vaccinated are those who have mothers who attend screenings and who are regularly followed by a paediatrician. Similar considerations come from data about the completion rates of vaccination. To recall, the vaccine is administered in a three-shot regime. Therefore, for full protection the completion of the series is needed. If we look at the few data existing on vaccine

completion, we observe that adolescents living below the federal poverty level are less likely to complete the vaccination series than adolescents living in richer households (Niccolai, Mehta, and Hadler 2011). These data, to be sure, are only beginning to emerge so we still do not know what of the three scenarios will result in the next decades. However, it is fair to conclude that these vaccination policies, so far, are targeting more those groups who have already the cultural and economic means to protect themselves against the risk of cervical cancer. If this trend continues it may exacerbate existing inequalities and thus going against the negative aim of justice indicated above. Besides consideration of justice, however, this approach may also have little epidemiological sense in terms of efficiency. Indeed, if this trend will persist, this approach potentially leaves out of focus those populations that are more at risk of persistent infections and, consequently, of cervical cancer. One could speculate that those girls who are receiving the vaccination right now are, in the vast majority, those girls that would have been anyway exposed to information about cervical cancer prevention, and that, perhaps would have undergone screening regularly. In very simple terms, if those who take the vaccine are also those that would have undergone screenings there is the risk that no reduction in incidence of cervical cancers will be observed in the future. An equitable distribution of the vaccine is thus worthwhile also in terms of epidemiological efficiency.

In summary, the positive aspects of the voluntary model, as adopted in the US, come from the recognition that individual choice in healthcare contexts is valuable and must be respected. Moreover, by providing federal funding to the uninsured, it also serves well justice, at least formally. Although the voluntary

model just described respects free choices it does so at the risk of worsening disparities. These policies indeed do not reach all groups equally, thus spreading knowledge and information to everyone who may need it, but only to those groups that have a positional advantage in terms of education and use of healthcare and preventive services. The voluntary model, however, can be implemented in different ways. Thus, a more precise analysis of its advantages and disadvantages requires a prior understanding of the other options.

4.2 The voluntary model in two European countries: the Italian and the British case

Italy: recommending HPV vaccination.

Similarly in Italy, HPV vaccination is offered free of charge to the target group (11-12 year old girls). Differently from the US, however, the enrolment system is more centralized and direct. All the families with an eligible girl for vaccination, indeed, receive an invitation letter by the local health unit that explains the benefits and limitations of the intervention, and proposes to those interested to contact either their local health unit or their paediatrician for administration of the vaccine. In Italy the population ethnic background is more homogeneous than in the US, but inequalities have long existed among the different areas since national unification in 1861, with the affluent north faring better than the south in several respects: economic, level of services, infrastructures, unemployment rates, and so on. As with the problem of racism in the US, a full description of the north-south divide in Italy would take too long, and would deserve a monumental volume by itself. Nevertheless, a few words may be spent to frame the problem. Two thirds of the Italian families

living under the poverty threshold reside in the southern regions. Of the 20.7 million people (36.1% of Italians) living in southern Italy, 7.3 million (35.4%) are poor. 4.6 million of these people live with less than €435 per month (Vecchiato 2004; Bonati and Campi 2005). With regards to the correlation between socioeconomic status and cancer inequalities in Italy few data are available. This is due, in part, to a lack of a comprehensive cancer registry covering a representative sample of the population. In Italy, cancer registries cover only 25% of the population with an uneven distribution between Northern (37%), Central (25%) and Southern Italy (11%)[29]. Although Italian data linking individual socioeconomic status and cervical cancer are not available, an international multicentric study including 20,000 women conducted by IARC, confirms that cervical cancer is associated with a low socioeconomic status – indicated by education and income level – and not solely by HPV prevalence (Franceschi et al. 2009). In other words, although HPV is equally distributed across the socioeconomic spectrum, its disease outcomes are not.

Some more specific considerations can be done, however, about the use of cervical cancer screening in the different areas of the country. According to the *Osservatorio Nazionale Screening* (ONS – The National Centre for Screening Monitoring) in 2009 only 39.3% of the women invited to screening actually attended it (Osservatorio Nazionale Screening 2011). The response, moreover, was unevenly distributed across the country, with women from northern regions much more likely to respond to the invitation than those from the south. Interestingly, basically all the southern regions are much below the

[29] The Italian cancer registry is serchable online at the *Associazione Italiana Registro Tumori*'s web site. Available at: http://www.registri-tumori.it/cms/. Last access: November 15th 2011.

national average, all the northern regions being instead above (see graph below). If we couple international data about the correlation existing between socioeconomic disadvantage and rates of cervical cancers with low attendance to screenings in those Italian regions where poverty is more present, we can speculate that also in Italy there exists the potential for cervical cancer inequalities.

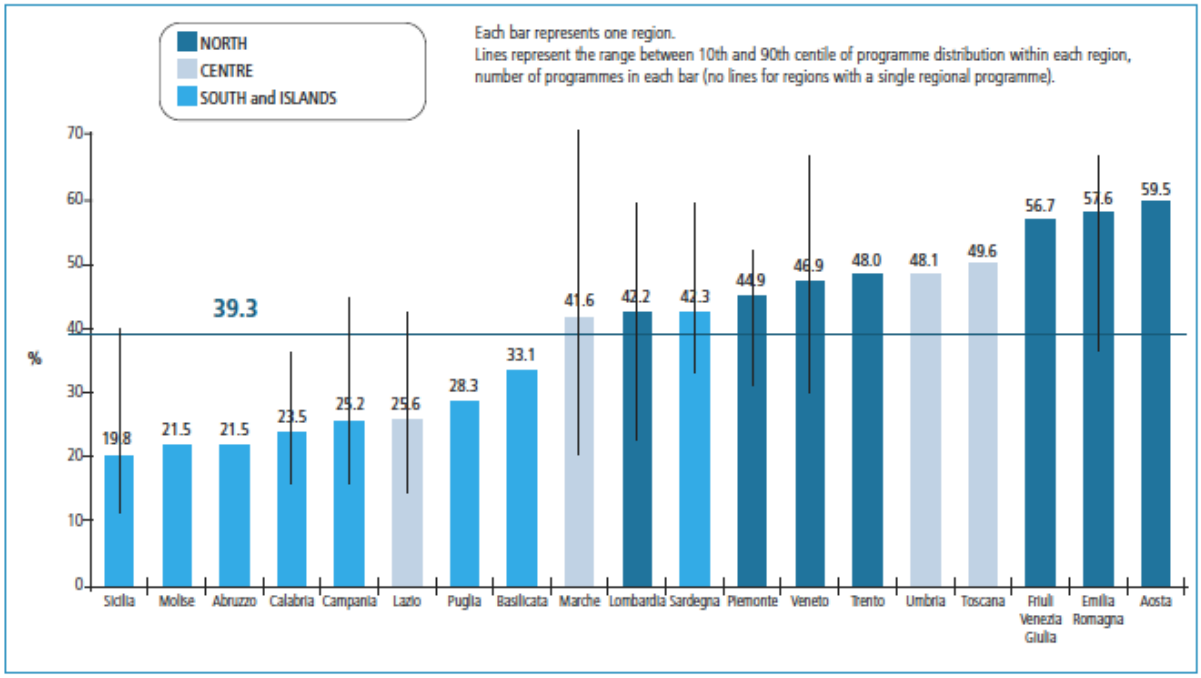


Figura 2. Adesione percentuale all'invito: distribuzione tra le Regioni. Survey su attività 2009.

Figure 2. Percent invitation uptake, by region. Survey of 2009 activity.

Graph 2: cervical screening uptake in all Italian regions. Drawn from (Osservatorio Nazionale Screening 2011)

Available data about vaccination coverage in Italy seem to confirm this trend. Since its national approval, in 2008, all the Italian regions have activated the free offer of the vaccine following the modalities indicated above. First, it has to be noticed that overall vaccination coverage in the whole country is still suboptimal. It is suboptimal both with respect to the objective established by the Piano Nazionale Vaccinazioni (95% by 2015), and also in epidemiological

terms. As I have indicated above, in order to have a sensible reduction of cervical cancers at the population level it is needed that about 75-80% of individuals in the target group get vaccinated. Official data about the coverage achieved by the end of the first years of vaccination show that only two regions approached that goal (Basilicata 80.7% and Puglia 80.1%), the national average being 63.4%. Among the regions that perform worse we find Calabria (54.4% coverage), Campania (50.1%), and Sicily (41.4%), three regions that are also among the economically weakest of the entire country (Giambi 2011).

Although results are suboptimal, and some disparities still persist among different areas, the Italian model seems to perform better than the US one. This is so in terms of overall coverage, that we saw being higher in Italy, but also with respect to the incentives given to overcome access barriers. In the US, indeed, we observed that motivation for initiating vaccination depended on recommendation by private paediatricians, or by the screening behaviour of the mother. That is, girls with mothers attending cervical cancer screening were more likely vaccinated than those who not presented this connection. Arguably, the preventive opportunity hence arrives only to those who are already within an established network of preventive practices. In the Italian case, instead, the recommendation and the relative information arrive to everyone, irrespective of the socioeconomic background. In this respect, it is an improvement on the US voluntary model. Yet, disparities in screening behaviour and in vaccination uptake existing between the more affluent and the most deprived regions need to be carefully monitored to comply with the negative aim of justice and to avoid that cervical cancer becomes a disease for the poorest. In summary hence, the Italian system accommodates parental autonomous choice by only

suggesting vaccination and leaving then acceptance to the private negotiation between parents and their physicians. In this way parents can decide, under the supervision of a medical professional, whether the intervention is in the best medical interest of their daughter and give a truly voluntary and informed consent. The system, moreover, offers an incentive as to overcome financial barriers by fully covering the intervention for all. In this respect, the programme equally addresses all the population. Nevertheless, the access barriers that are present also with regards to cervical cancer screening are not completely eliminated, with suboptimal and unequal uptake. The latter, while contributing only partially to the population goals, risks creating patterns of inequalities.

United Kingdom: a school-based approach.

In the UK, the third element of my comparison, the vaccine is administered through a school-based programme. That is, vaccination is proposed in a school setting by school nurses to the parents of all eligible girls (12-13 year old) through a form that explains vaccination, its benefits and modality of intervention. As shown above, the vaccination is part of the NHS vaccination service and is thus offered free of charge to the target group. As in the other settings, also in UK the economic barrier to vaccination is overcome by financial incentives provided by the state.

Although in the UK the population ethnic background is more mixed than in Italy, also in this context there appears to be no identifiable pattern of health inequality travelling along this axis (Muennig and Murphy 2011). In a study performed on all England cancer registries for cancer mortalities in 1998-2003, Shack et al. (2008) note that the highest cervical cancer incidence rates occur

among the most socioeconomically deprived groups. They further notice that incidence decreased consistently with increasing affluence. They conclude that, if all groups had the same incidence rates of the most affluent, 4,108 (28%) fewer cervical cancer cases would have occurred in those years (*ibid.* 271). In line with the IARC multicentric study presented above, an English research suggests that socioeconomic status is linked with higher rates of cervical cancers but not with higher HPV prevalence. Moreover, screening uptake has been reported to vary by socioeconomic status and be lower for women with low levels of education (Baker and Middleton 2003; Sutton and Rutherford 2005).). In this respect, also in the UK is present a gradient in cervical cancer incidence as the one shown in the US. This data together show once again that although the initial trigger of cervical cancer, that is HPV, is widespread across all the societal strata, its disease related outcomes are not. In the concluding remarks of this chapter I will make some specific considerations as to why an equal distribution of the intervention is important also from the epidemiological point of view. For the moment, however, let us consider how the school-based system fares with respect to parental autonomy and the negative aim of justice.

The school-based system apparently scores better than the other voluntary models with regards to justice. As all of them it proposes financial incentives to all eligible individuals – 12-13 year old girls – but differently from the others it also offers facilitations in accessing the intervention to all. In the US we saw that although the vaccine is free to uninsured children via the VFC, at the end those who access the intervention are those children who already have established contacts with their paediatricians, or who have mothers that regularly attend

cervical cancer screenings. In Italy instead, although this initial access gap is closed by the active invitation to all by the invitation coming from the local health units, still some barriers with regard to access exist. Also in Italy, indeed, the disparities in screening attendance existing between the most and the least affluent regional areas seem to come up again, although in minor form, in the case of vaccination uptakes. In the UK, instead, the programme seeks to overcome not only the financial barriers, but it also provides a space that is *de facto* easily accessible to all. Indeed, in UK education is compulsory until age 16, thus a school based programme is able to track all individuals in an institutional space specifically devoted to the distribution of one of the most important public goods - that is, public education. In practical terms, the school-based programme facilitates uptake. Parents do not need to get prescriptions, leave work, or arrange to bring children to a clinic to receive the vaccine. The advantage of distributing vaccination in schools is, moreover, accentuated by the fact that the final users of the intervention -12-13 year old girls and their families -are most likely known by the institution in several ways. In schools, indeed, girls and their families are not merely a number in the registry of the local health unit but clearly identifiable individuals with specific socioeconomic backgrounds and family's conditions. In other words, in the school environment the users of the interventions are, at least ideally, extensively known in their biographies. Accordingly, it is easier, at least in theory, to make the vaccination offer really available to anyone, and to spot personal circumstances of systematic disadvantage more easily than in the other two models. Vaccination made routine in a school-based setting appears to be also efficient in terms of the objectives needed to obtain population health goals. Official data by the Deparment of Health states that in 2010 77.5% of the UK 12-13 year old girls

received the vaccine (76.4% in England, 86.9% in Scotland, 77.3% in Wales, and 83.4% in Northern Ireland), faring better than all European countries. Important for my purposes here, is that no disparities in uptake are observed between the most affluent and the most deprived areas of the country (Sheridan and White 2010). Arguably, these data show that the school based system in being efficient also serves the negative aim of justice.

Some concerns with the school-based model, however, may be raised with respect to the way it actually respects parental autonomy, and whether informed consent is achieved in practice. This point is raised by (Malmqvist et al. 2011) who notes that the school setting is likely to convey the wrong impression that the vaccine is compulsory like many things happening in schools. Rather than facilitating comprehension and achieve voluntary adhesions, hence, the school-based programme would look more like a kind of soft coercion. As they recognize, this problem could be avoided by if extensive information is given to parents, but the thight schedule of the administration (to recall, the vaccine is given in three shots over three months) would make it difficult to allow parents the desired time to reflect on it and decide only after they are genuinely convinced about their choice. In a same vein, they speculate that insisting too much on the voluntarity of the intervention may rise suspicion about the programme (*ibid.* 24). The problem is certainly relevant and may make the achievement of informed consent a daunting task. Nevertheless, in the UK system specific evening meetings are devised in schools so to inform parents about the progamme and its meaning. This aspect partially mitigates these concerns. But, clearly, it very much depends on how they are actually

performed. To understand this point is important to see how the informed consent process is mediated in practice.

Fundamental in this process are school nurses that: collect the consent forms, are open to answer questions by concerned parents and, finally administer the vaccination. In a very recent paper collecting nurses' views on the first year of the HPV vaccination programme in the UK (Hilton et al. 2011), school nurses report four kind of parental attitudes towards HPV vaccination. The first was of active acceptance. That is, several parents were positively participating to the programme and contacting them for more information and reassurance. The second was passive acceptance. Many parents simply signed the form without much involvement and further questioning. The third typology of parental attitude was, instead, one of passive rejection. In some circumstances, parents did not sign the form out of apathy and not for specific concerns. It is reported that, in these circumstances, further efforts were spent to contact these parents, explain better the benefits of the vaccination, and ask reasons for refusal. Another attitude noticed was one of active rejection. Active rejectors were those parents that attended evening sessions dedicated to the explanation of the programme and challenged it alleging that their daughters were used as "guinea pigs" (*ibid.* 226). This last point deserve some comment in line with some thoughts I have put forth in the first chapter, when I was speaking about civic membership. In these contexts indeed, parents are able to express their views, expose their concerns, and being heard by others that may have different views. What these spaces are offering, clearly, is not full politcal participation in the devise of the programme itself, nor do they necessary lead to a flattening of dissent. As one study shows (Stretch et al. 2009), several parents attending

these meeting went with a clear idea as to whether to allow their daughters to get the vaccine, and rarely changed it. Nevertheless, these spaces permit dissent to circulate in an informed institutional setting and, perhaps, also serve the scope to make more informed choice. More generally, these procedures allow the parents to enhance the informational base for an autonomous choice.

To summarize, the UK system appears as the least voluntary among the three programmes. Indeed, by organizing the whole programme in a routinized manner, some concerns may be raised as to whether parents are able to truly consent to the procedure. This is so because of the tight timing of the vaccination schedule and because schools may give the impression that the scheme is compulsory. Nevertheless, on the positive side, the programme better achieves the population goals than the others and does so in an equitable manner. Moreover, by providing an institutional space in which to discuss the programme and how it will affect them and their daughters, the programme seems to be better positioned than the others in letting information about HPV to circulate in an informed context and to the benefit of all.

5. Concluding remarks

In this chapter I have provided a normative overview of the different approaches taken so far to control HPV infection and reduce the incidence of cervical cancer. I have done this by differentiating the models according to how they interfere with people's autonomous choices and how they fare with respect to justice. I have shown that a purely mandatory model is hardly justified through the now classical tools of the harm principle, nor is it justified as a case of soft paternalism. In the spirit of the beneficence model of public health ethics, hence, I have tried to understand whether the least restrictive

alternative was instead more easily justifiable. Among the options presented, the least restrictive alternative is by far the voluntary model as adopted in the US. This model, although attractive for the respect it pays to parental autonomy also has some drawbacks. In particular, I have identified as most relevant those pertaining to the negative aim of justice. Although the campaign is still in its infancy, the few available data we have about vaccination uptake suggest that those who are taking advantage of the intervention are those people who are already embedded in a network of preventive and medical relations. This model, hence, while preserving freedom of choice may run the risk of exacerbating existing inequalities and fall short of long term efficiency. Slightly more intrusive means, like in the Italian case, appear to score better from the perspective of justice while also preserving autonomous choice. This model is respectful of autonomous choice and, in a sense, it is also autonomy enhancing, in that it offers - via a recommendation letter – to everyone the opportunity to know more about the preventive option. In its specific context, however, is still performing sub-optimally from the point of view of efficiency and the perspective of the negative aim of justice. All these problems seem to be overcome by rendering vaccination routine while still respecting the choices of individuals in the school-based model. Although some remarks can be done also about the latter, especially with regards to the difficulty of obtaining valid informed consent, the school-based model is able to create, at least ideally, a space for expanding the autonomy of all in an institutional setting.

These remarks, however, also show how an insistence on the least restrictive alternative may not be a sufficient ethical justification of public health policies. As we have seen, the US voluntary model is certainly the least restrictive

alternative among all the policy options presented. In these regards, one would be also tempted to conclude that is the one that allows more space for the exercise of free choices. Nevertheless, if we recall the concept of freedom as it stems out of the republican model, we realize that this conclusion does not necessarily hold as valid. As we saw in the first chapter, conceiving freedom as non-interference only is not all there is to say about the concept. In a sense, all those families who are not reached by the intervention, perhaps because they are not into a network of established medical and preventive practices, are certainly free from any interference. Yet, I would resist concluding that their choice was effectively free in a non-dominating sense. Indeed, conditions of socioeconomic disadvantage also imply barriers as to the access to adequate information and to those places in which information can be enacted in services in the interest of individuals so situated. Therefore, those programmes that try to reach all in a more intrusive way (i.e. the Italian and the UK models) are not doing it in an arbitrary way but, arguably, to track everyone's avowable interests. It is only after that the interests of all have been tracked that choice becomes really autonomous and, as such, worthy of respect. The Italian an the UK model therefore appear as those who are better able to take into account those interests without the disvalue of coercion of a mandatory model with group-specific exemptions. Although this similarity needs acknowledging I have also noticed that an invitation letter may be only formally just. In this sense, the school-based model provides further warrant that all people have been adequately reached by the campaigns. In contexts in which large inequalities exist, hence, the school-based model may be the most preferable option to choose. At least so if we admit, as I think we should, that concerns for justice need to inform public health policies.

Chapter five: Should the HPV vaccine be given to men? Gender equity vs. efficiency

1. The sex of cervical cancer

In the previous chapter I have explored the ethical dimension of the different policy means so far proposed to tackle HPV infections and reduce the incidence of cervical cancer. I have noticed that all the models identified differently put in balance the moral concerns at stake in the issue. In particular, I have noticed that an insistence on the least restrictive alternative alone leaves out of focus important concerns for social justice and the need to avoid the worsening of existing inequalities. Although the contextual aspects of any policy have, clearly, to be taken into account, the school based programme looked as the one allowing broader space for the recognition of all the interests at play. If one wants to draw a more general conclusion from the comparative exercise performed above is maybe that the morally preferable alternative is not necessarily the one that allows more space for non-interfered choices, but one that, while allowing the free exercise of choice, also offers the opportunity to enlarge the informational basis on which individual choice is made and that does it in a way that is accessible to all. In other terms, not all individuals in society are equally placed with regards to the information available and, consequently, a policy that does not reach everyone, in some way, is not really providing the space for a truly autonomous choice. In this respect, the school-based system seems to create the space for respecting choice and expanding the autonomy of all. In this sense, it also meets concerns for equity and justice.

A common thread among these policies, however, is the group they identify as the privileged target of the intervention. All policies indeed pursue a gender-based strategy. In its direct-to-consumer campaign Merck, the company producing Gardasil, addresses mothers and their daughters urging them to make the right choice: buy the vaccine and be 'one less' cancer victim. Its marketing strategy, comprehensibly, was to catch the attention of middle class women who were aware of the risks of cervical cancer and, more importantly, had the economic means to afford such expensive vaccine. The whole advertisement campaign, indeed, was centered on the idea of emancipated mothers and daughters that were now provided with the tool for a full protection against the perils of sexually transmitted infections. An analysis of marketing strategies is not of my specific concern here (for an interesting one see: Mamo, Nelson, and Clark 2010), but the idea that HPV and cervical cancer protection is, in essence, women's business has permeated also scientific commentaries. In one passionate editorial appeared on *HPV Today* – a periodical newsletter for medical professionals – and tellingly titled 'The sex of cervical cancer', Xavier Bosch affirms:

> HPV is a significant human carcinogen for both men and women. However, organ-to-organ susceptibility is strikingly diverse and the number of HPV-related cancers is strongly skewed, with women carrying the heaviest burden. The central public health impact of HPV-related cancers is thus first and foremost a woman's issue (X. Bosch 2009, 2)

To be precise, Bosch is one of the most prominent figures in HPV research and to him and his group of collaborators is due much of the epidemiological knowledge we now have about the virus. In this sense, his is not a claim for

suggesting that HPV prevention is a private issue for women. Nevertheless, he takes policy actions aimed at the control of HPV as manifestations of the importance that women's issues have now acquired in our societies. As he claims, this importance "also reflects the power and influence of women in the decision-making process" (*ibid.*). Although I largely share this view, it remains to be seen whether this acquired importance implies necessarily a gendering of the issue. As I have shown extensively throughout the previous chapter, not all women have the material and cultural resources to have full access to the benefits of the intervention. In other terms, if it is true that women's health has acquired major importance in the current medical and preventive landscape, it should not be forgotten that women are not a homogeneous group, and not all of them are so empowered to face HPV risk properly. Framing the whole problem as a woman's issue only may thus be limitative and can have the effect of obscuring the multifaceted dimension of HPV prevention. In the context of the comparative analysis, I insisted that concerns for socioeconomic status are as important as classical ethical concerns for respecting autonomy. In the present one, I would like instead to focus on the ethical implications of gender-based programmes.

HPV infection, indeed, is sexually transmitted. As such, it is an issue for everyone, at the very least for everyone who is also sexually active. Thus a point can be raised as to whether it is right to include only girls into the programmes. This point can be put forward from two perspectives, one based on epidemiological reasons, and the other on grounds of gender equity. From an epidemiological perspective, in general, makes perfect sense to increase the population of the immune individuals so to reduce rates of contagion. After all,

the vast majority of vaccination programmes devised in the history of public health followed this strategy. That is, vaccinating as many people as possible so that the likelihood of an epidemics falls down dramatically. The epidemiological reason, however, is supported by broader concerns about how such female specific endeavours impact on morally sensitive issues like relations between genders. In other words, it can be argued that, given the sexual nature of the infection, the burden of the preventive intervention should be shared between the female and male population. One does not need to be a woman, a feminist, or an epidemiologist (or possibly a combination the three) to understand that by concentrating our attention to women only part of the picture is still missing. Men, although suffer the ill effects of HPV less frequently than women, are still vectors of the infection, and so it makes sense to think that they should share part of the preventive responsibility. This option, however, proves problematic because the HPV-associated burden of disease is heavier on women than in men. It would be unfair, one may think, to vaccinate males only for the epidemiological benefits this option would bring about to women. It would be so because they will not have much to gain and, perhaps more importantly, because this choice would divert energies and funds from attempts to reach all the girls that may benefit the most from the vaccine. This aspect gains even more argumentative force when we consider the high cost of the vaccine and the ensuing financial costs a more inclusive campaign would require. Several models developed to calculate the cost-effectiveness profile of HPV vaccination have indeed underscored how such an inclusion may provide little additional benefits at a high cost as compared to the strategy of vaccinating a high number of women only. In terms of the trade-offs indicated in a previous chapter, hence, HPV-related public policy finds itself confronted with a choice between issues of

equity and efficiency. So far, the latter considerations seem to have prevailed and little attention has been paid to equity concerns. In this chapter I explore this trade-off, specify the ways in which it arises, and then assess what are the reasons in favour and against the inclusion of males into the programmes. In particular, I will assess whether these reasons are strong enough to hold notwithstanding their policy implications would have an alleged low cost-effectiveness profile. I will explore the options and see whether there are moral reasons to extend the programmes to males too. Before doing that, however, it is important to see whether the HPV-associated disease burden is a woman's issue only.

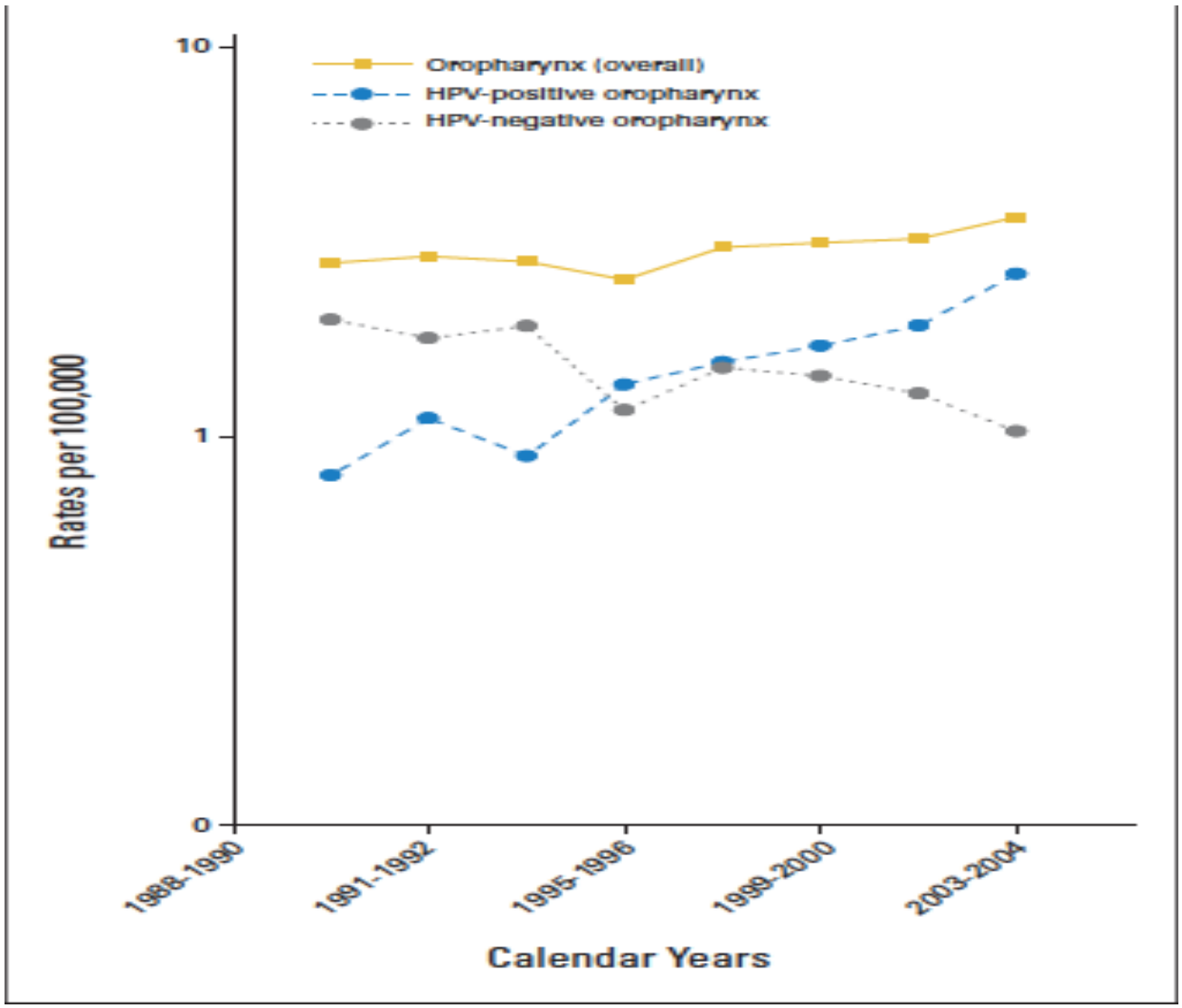
2. HPV-related cancers: A woman's issue?

Cervical cancer has long been a scourge for women's health affecting their life and reproductive plans. Before the introduction of massive preventive campaigns through screening, this tumour affected women with a high incidence of about 35 per 100,000. Although the incidence of cervical cancer is now reduced in all those countries in which organized preventive campaigns are present, it is still a major cause of mortality for women as a group. Knowledge about the link between this disease and its viral causative agent is relatively recent. Even more recent is the possibility of adopting vaccines as preventive tools. It is reasonable then that these vaccines have been immediately perceived as further elements for combatting this illness and, possibly, eliminating it. In this sense, HPV vaccination campaigns entered an already established network of preventive efforts, professional expertise and technological structures aimed at cervical cancer prevention. Tradition, we know, is very important for human activities. It determines practices, and

suggests intervention criteria and plausible plans of action. When an innovation enters these patterns of established practices, however, it may restructure known categories and interpretative schemes. This is also true for biomedical innovations as they unravel the causal roots of diseases and offer new ways for their control. Besides being a relevant issue for biomedical practice, the latter, may also have ethical and social implications that need to be considered alongside. HPV offers a paradigmatic example of this dynamics as it asks us to enlarge our focus from disease, after it has occurred, to its causal roots. Now that this change in perspective has taken place, biomedical and epidemiological research is progressively ascertaining that HPV-related disease outcomes are not only confined to the cervical site but affect, although to a minor extent, men too. HPV, in fact, plays causal role also in other tumours in the anogenital area (vulva, vagina, penis, anus) and in a subset of head and neck cancers. Let us thus understand better what is the HPV-related disease burden for men and its weight. HPV associated head and neck cancers and anal cancers are of particular interest for this work. Therefore I will discuss them in order.

Head and neck cancer is a term that covers epithelial malignancies that originate in the nasal cavity, oral cavity, pharynx and larynx. It is the sixth most common cancer worldwide, and accounts for about 650,000 new cancer cases and 350,000 deaths every year (Argiris et al. 2008). Known risk factors for head and neck cancer are cigarette smoking and high alcohol consumption. Although an overall marginal decline in the incidence of most head and neck cancers in recent years, the incidence of oropharyngeal cancers has increased, especially in the developed world. This increase has been observed despite a drastic overall reduction in cigarette smoking in those countries where anti-tobacco

campaigns have been conducted. Oropharyngeal cancers, it has to be reminded, are just a subset of all head and neck tumours, and they can be distinguished in HPV positive and HPV negative. Recent studies are ascertaining that while the latter are decreasing due to a reduction in cigarette smoking, the former are instead increasing at a rapid pace. The two tumours, moreover, appear to be distinct clinical entities in different respects. HPV negative oropharyngeal cancers tend to occur at an older age (around 60 year old) and affect individuals who present cigarette smoking or alcohol consumption as risk factors. HPV positive tumours, instead, tend to come about at a younger age (40-50 year old age group) and affect individuals who do not present standard risk factors, but young age at first sexual intercourse and 4 or more of lifetime oral sex partners. HPV, indeed, is thought to be transmitted also through the orogenital route. Moreover, it is observed that HPV positive patients have better prognosis than HPV negative patients (Mehanna et al. 2010; Chaturvedi et al. 2011). The graph below shows well this trend. The dotted yellow line indicates the incidence rate of oropharyngeal cancers overall, whereas the blue and grey lines indicate, in turn, HPV positive and HPV negative oropharyngeal tumours. As we observe, while the overall incidence of these cancers has increased from the late 1980s to the early 2000s (from 2.8 per 100,000 per year to 3.6 per 100,000 per year), the incidence of those tumours linked with the 'standard' risk factors has decreased in the same time frame (from 2.0 per 100,000 to 1.0 per 100,000). HPV positive oropharyngeal tumours, instead, are sharply rising in incidence (from 0.8 per 100,000 to 2.6 per 100,000).



Graph 3: Incidence trends of oropharyngeal cancers in the US. Drawn from: (Chaturvedi et al. 2011)

The study cited was based in the US, but similar trends are observed also in other countries. The UK, for instance, has seen a 51% increase of HPV positive oropharyngeal cancers (Mehanna et al. 2010). A recent retrospective study conducted in Sweden in showed a progressive increase in the detection of HPV in oropharyngeal cancers over the past three decades (23.3 in 1970s, 29% in 1980s, 57% in 1990s, 68% in 2002, 77% between 2003 and 2005, and 93% between 2006 and 2007) and led the authors to observe that we are probably experiencing an epidemics of viral-induced oropharyngeal cancers (Näsman et al. 2009). In an interview to *Medscape Medical News Oncology*, the authors of the

US study speculate that this sharp increase of HPV positive oropharyngeal cancers may be a legacy, at least in the US, of the sexual revolution occurred in the 1960s and 1970s. As one of the authors told to *Medscape Medical News Oncology*: "It is clear that the strongest behavioural risk for HPV-related oropharyngeal cancer is the lifetime number of oral sex partners. Our own work shows a strong cohort effect, which means the greatest determinant of risk in any age group is the year that you were born. These cohort effects are largely driven by societal changes, and they tend to affect people first who are younger, because they are the people leading the behavioural changes" (quoted in: Chustecka 2010, 2). Reasonable speculations aside, what it is important to show for the purpose of this section is that these HPV positive oropharyngeal cancers tend to affect men more than women. In the US, the only country for which absolute numbers are provided about HPV positive oropharyngeal cancers, the *Centers for Disease Control and Prevention* calculate that every year 10752 people are diagnosed with HPV positive head and neck cancers (oropharyngeals being the vast majority) and 8530 of these occur in men[30]. These data already show that HPV prevention need not being a woman's issue only.

Nevertheless, another set of HPV-related tumours calls for our attention, perhaps even more. It is the case of HPV-related anal cancers. According to the

[30] Data about currently available vaccines' ability to prevent also these cancers has not been confirmed yet through clinical trials. This fact notwithstanding, their efficacy at these sites is biologically plausible. In fact, the HPV vaccines are: a) equally immunogenic in boys and girls (Reisinger et al. 2007), b) effective in both sexes against lesions at genital mucosal and cutaneous sites (Garland et al. 2007; A. R. Giuliano et al. 2011), c) able to foster systemic humoral immune response, that has been shown to be important for protection (Stanley 2006). Nevertheless, no data are available on anatomic site specificity of the vaccines. Definite proof about their efficacy at sites other than anogenital may come either directly, from clinical trials yet to be performed, or indirectly, by observing whether the number of HPV positive oropharingeal cancers will decrease in the next decades in vaccinated versus non vaccinated women/men.

Centers for Disease Control and Prevention, in the US 4403 individuals are diagnosed with anal cancer and 2842 of them are found in women and the rest on men. Despite being very rare in the general population, about 1.5 per 100,000 every year, anal cancers are relatively frequent in homosexual males or, as this group is called in the medical literature, in the epidemiological class of males who have sex with males (MSM). It is estimated, indeed, that in this population the actual incidence of HPV positive anal cancers ranges between 12.5 and 36.9 per 100,000 per year (Daling et al. 1982; Palefsky et al. 1998; Daling et al. 2004), roughly the same incidence rate observed for cervical cancer before industrialized societies took huge efforts to reduce the burden of that disease. These data suggest that also among men there is a subgroup of people that are at risk of suffering the ill effects of HPV infection and thus may benefit from the intervention should males be included in vaccination policies. The table below shows the overall HPV associated cancer burden in both genders in the US.

Incidence Counts and Rates of Potentially HPV-Associated Cancers by Sex and Site, 2003–2007

Cancer Site	Average Number of Cases per Year		Incidence Rate per 100,000 Persons	
	Male	Female	Male	Female
Cervix		11,607		7.78
Vulva		2,951		1.80
Vagina		691		0.42
Penis	987		0.76	
Anus	1,561	2,842	1.14	1.76
Oropharynx*	8,530	2,222	5.97	1.38
TOTAL	11,079	20,313	7.87	13.15

Table 3. taken from the *Centers for Disease Control and Prevention*'s website[31]

[31] To be found at: http://www.cdc.gov/cancer/hpv/statistics/cases.htm (Last access: November 15th, 2011)

As we see, the HPV-related cancers in males represent nearly one third of the disease burden. Regrettably, such precise data are available for the US only and one can only speculate that in other countries the same proportions are observed. Nevertheless, we know that HPV infections are more or less equally present in all countries with similar cultural backgrounds and robust healthcare systems. It is not wild speculation, hence, to suppose that these data can also be representative of a general phenomenon, although imprecisely. The fact that these data are missing is though an indication that not enough attention is paid to the male issue when we think of HPV and cancer prevention. Indeed, while it seems that HPV infections and associated cancers cut across gender differences, preventive campaigns, as shown, do not.

Men are HPV vectors thus actively contribute to rates of infection and ensuing diseases in women. As we have seen they also share, although to a minor extent, some ill effects of the infection. Accordingly, it is possible to claim that men as a group have a moral responsibility and, at least *prima facie*, an interest in being vaccinated. Also women, moreover, may share these interests in that by vaccinating men it would be reduced for them the likelihood to be exposed to HPV. The question therefore becomes: should HPV vaccination policies include boys in their preventive strategies? To the analysis of this point I now turn.

3. Gender equity, cost-effectiveness, and their moral opportunity cost

Intuitively, gender-based distinctions as to the access to benefits and burdens of medical resources are morally objectionable. However, it is important to assess whether this intuition applies to the HPV case too. In the previous section I have

indicated that there are reasons for taking into account also males in the programmes. I did so by showing that there is, at least at first approximation, an interest in the male population in taking the benefits of the intervention. Expanding HPV vaccination campaigns to the whole population, thus abandoning current gender-based approaches, would prove also beneficial for women as a group because it would greatly reduce the proportion of individuals who are vectors of the infection. In this sense, for any individual it would be far less likely to encounter the virus and, eventually, developing HPV-related diseases. Expanding the programmes would thus maximize the public health impact of the intervention by bringing about herd immunity effects. As we saw along the lines of the first chapter, the creation of herd immunity is a public good, that is, a good that is open for all to enjoy. In public health ethics the provision of public goods is what most clearly justifies public health activities (Verweij and Dawson 2007; Anomaly 2011). Nevertheless, this justification enters public health deliberation only in certain respects. Indeed, if it is true that the provision of a public good is one of the reasons that render a public health activity worthwhile, this does not imply that the very possibility of its introduction trumps all other considerations. As shown in the previous chapters, some of these considerations have to do with what are the right means to bring about a public good in a way that is also respectful of individual choices and that responds to demands of social justice. Here, instead, I address those considerations that may function as limits to the provision of public health goods from the perspective of public health departments themselves. Indeed, healthcare and preventive goods competes for resources with other goods that can be provided at the societal level. The resources that are used in healthcare and preventive services are finite: more of these resources can be

devoted to the production and delivery of preventive services only by diverting them from some other use, either outside or within the health budget. This suggests that choices have to be made and that few, if any, goods can be supplied with no restrictions. The nature of choice and the inevitable trade-offs encountered in making these choices are captured in health economics by what is called opportunity cost, defined as: "The opportunity cost of committing resources to produce a good or service is the benefit forgone from those same resources not being used in the next best alternative" (Morris, Devlin, and Parkin 2007, 3). Opportunity cost of healthcare and preventive programmes, even included vaccinations hence, is generally calculated in terms of their cost-effectiveness. Cost-effectiveness of an intervention comes in degrees. That is, it is generally established a threshold of monetary value that is worth spending for any additional unit of health benefit brought about the intervention. An intervention that goes above that threshold is considered not cost-effective, one that goes below that threshold is instead considered cost-effective. In other words, the decision of whether a public health intervention is worthwhile is generally balanced in terms of the population health impact it may bring about and its opportunity cost in terms of cost-effectiveness. The latter defined as: "the additional cost required per additional health benefit produced as compared with the next most effective alternative" (Kim 2011, 1760).

Models that have evaluated both the population health impact and the economic profile of different scenarios of intervention suggest that an inclusion of males into the programmes may not be cost-effective as compared to programmes, such as those presented in the previous chapter, that target only females.

Let us see, then what are the different scenarios so far evaluated and what they request for a programme that is both epidemiologically sound and economically attractive. The models are mathematical simulations that tell us what would happen if certain conditions applied. In this sense, they are important guides for effective decision-making. In particular, three scenarios seem to emerge from the studies conducted so far. I will discuss these three scenarios by discussing more in detail the way they emerge in one of these studies.

This study, published in the prestigious *British Medical Journal* (Kim and Goldie 2009) has investigated the cost-effectiveness of including boys into HPV programmes in the US under different scenarios. The model calculates, more specifically, incremental cost effectiveness (ICE) per QALY (Quality Adjusted Life Years) of hypothetical kinds of vaccination campaigns. QALYs are a health economic metrics attributing weights to life years brought about by an intervention. QALYs have a weight comprised between 0 and 1 (where 1 is the value given to full health and 0 to death). ICE - a measure used in health economics to assess whether a strategy is cost-effective - is the ratio of (i) the difference between the cost of the strategy under analysis and the next less costly strategy to (ii) the additional health benefit measured in QALY. Various thresholds are used in different context to determine when an intervention is cost-effective. In the context evaluated by the study interventions with ratios below $50,000 or $100,000 per QALY gained are considered good value for money.

The study, graphically summarized in the table below, shows various things. First, vaccinating 75% of males and females in the age group 11-12 (scenario A below) would always be less cost-effective than vaccinating only girls. However,

the option of including boys in the campaigns becomes progressively more attractive as coverage of girls is assumed to decrease, and all HPV-16 and 18 health outcomes (rather than just cervical cancers) are taken into account. Vaccinating both sexes with coverage of 50% was found to have ICE per QALY gained of $ 62,070 under the most favourable assumptions; namely, when vaccine efficacy for other HPV-related outcomes was considered to be high and lifelong (scenario B). Interestingly, the ICE of including boys into the programmes becomes even more attractive when the price of the vaccine is slightly lowered. Under all circumstances, vaccinating 75% of girls only is more cost-effective in the model (scenario C). Other studies, moreover, tell us that while scenario A and B will bring about herd immunity effects in the short or mid-term respectively (Lehtinen et al. 2008), female only scenarios (like C below) may require increased coverage to 85% to achieve herd immunity in the long-term (60 years) and assuming heterosexual patterns of behaviour only (Choi et al. 2010).

	SCENARIO A	SCENARIO B	SCENARIO C
OUTPUT	SAME REDUCTION IN HPV 16 AND 18 MORBIDITIES		
COVERAGE	75% GIRLS AND BOYS	50% GIRLS AND BOYS	75% GIRLS
TIME FRAME	SHORT TERM	MID TERM	LONG TERM
COST (ICEXQALY)	$ 114,510	62,070	20,990

Table 4. Data drawn from: (Kim and Goldie 2009)

It must be noticed that the model presents us with hypothetical scenarios, and tells us what would happen if certain conditions applied. In this respect, the model does not represent an actual state of affairs. Although the study is very accurate at analysing different scenarios for which we still lack clear evidence, as for instance whether or not vaccine efficacy is life-long, it fails to account for important aspects that might prove useful to direct policies. Among them, the model misses to take into account patterns of homosexual behaviour.

Another limitation of the study is spatial, so to say. That is, the model takes into account epidemiological data and patterns of sexual behaviour gathered from the US population. Accordingly, its results can inform sound policies with respect to that country alone. This fact notwithstanding, similar scenarios can be found in models coming from UK (Choi et al. 2010), Finland (Lehtinen and Paavonen 2009), and Italy (Mennini, Giorgi Rossi, et al. 2009). The latter

limitation, however, is of no much ado for my purposes. I will assume, indeed that the three scenarios are plausible and ask a more general ethical question. The scenarios presented, indeed, although plausible will require decades of sustained immunization in the privileged target group in order to bring about the desired effects. All campaigns, however, are still in their infancy and the data about coverage presented in the previous chapter suggest that, perhaps with the exception of UK, uptake is still far from being as high as required. Moreover, the achievement of valid population health goals that are also cost-effective requires constant efforts to sustain adequate coverage over the years. The ethical question, thus become: who should fill the gap to achieve public health goals? Should we adopt a fully utilitarian strategy and then going for the more cost-effective solution? Or should we also value issues of equity thus opting for a gender-neutral campaign? More precisely: should we put societal pressure on women so to reach and sustain high coverage on that population, or should we try to target, for instance, 50% of both sexes?

In what follows I indicate what are the reasons for maximising inclusiveness in the male population too. In an attempt to answer this question it should be admitted from the start that the benefits the intervention may produce are greater for women as a group. Accordingly, they have more reasons than men in being vaccinated since it is in their best interest to do so. After all, the incidence of cervical cancer is higher than other HPV-associated cancers affecting men too. A policy targeting only women, it can be argued, would be justified because it would be aimed at reaching those individuals that need it the more. A pragmatic issue, moreover, adds up to this motivation. As extensively shown in the previous chapter, in many contexts it has so far proven difficult to reach

sufficiently large numbers of women. Therefore, trying to reach also men may result in a waste of efforts and material resources. In other words, the resources needed to restructure current policies could be better employed as to improve uptake in the current target population. Nevertheless, if these attempts are based on the presupposition that it is in women's best interest to be part of the programme then they run the risk of being unjustifiably paternalistic. That is, these attempts arbitrarily ascribes what are the right choices a person should be willing to make about her personal life and her future. Of course, one could agree with the idea that there are indeed good reasons why a woman should take personal advantage by immunising herself against HPV. However, the fact that it might be in the best interest of women to take the vaccine does not necessarily imply that public health officials are legitimated to put pressure only on this group to achieve cost-effective public health goals. It should be also taken into account that, sometimes, there might also be strong reasons for some women or their families, not to join the campaigns and good reasons for some men to join. Gender-based programmes, indeed, may be mistakenly based on the assumption that males, as a group, do not have other-directed reasons for being vaccinated as a way of protection of the female population through herd effects. Although we live in an age in which individualized approaches to care and prevention are given, rightly, much attention, we should not exclude the possibility that some families may find it reasonable to vaccinate their sons if properly informed not only of the benefits the intervention may have also for males but also about the fact that males still remain vectors of the infection. A public policy aiming at population health cannot exclude, at the outset, that people's action are never informed by altruistic motivations. Nor these motivations need to be fully altruistic. As shown, cervical cancer is one of the

most frequent in young women aged 15-44. Premature death, disturbs family dynamics and, with it, the lives of husband, partners and children.

Anyway, even if we dismiss the charge of paternalism and the possibility of other-directed interests males may have for joining the programmes as insignificant, the strategy of targeting girls only – although plausible – still would not come without costs, perhaps indirect.

Some commentators show how public policies, besides their primary objectives, carry with them also a set of cultural meanings and symbolism that, intentionally or not, can influence attitudes and behaviours of the public. Public policies, in other terms, have also an expressive function. As Pierce puts it: "policies may reinforce an existing norm or they may seek to refine, modify or create a norm" (Pierce 2011, 54). One example of this phenomenon, as reported by the legal scholar Cass Sunstein, is regulations against hate speech in the US. According to Sunstein, the central purpose of this law is not solely prohibiting hate speech as such, but also to convey the meaning that bigoted attitudes are unacceptable in a liberal society (Sunstein 1995). Pierce, in the same vein, comments that public policy operates on many levels and "while aiming to achieve a particular objective or outcome, it can also be a valuable tool for achieving other important social goals" (*ibid.* 53). To come back to our case, gender-based HPV vaccination programmes may reinforce or create the social meaning that sexual health is a woman's issue only thus incrementing infelicitous gender stereotypes. After all, as noticed by scholars of feminist orientation, women already shoulder a disproportionate burden in issues related to reproductive decision-making (de Melo-Martin 2006). A gender-based programme, therefore, may send the message to young people that

women are responsible for managing sex and that men are allowed to take less responsibility on those issues. Some studies report, moreover, that HPV testing causes distress and psychological anxiety in many women. Because of its association with sexual intercourse, some women see HPV infection as a social stigma, especially if they live in a sexist familiar setting (McCaffery et al. 2006). In this respect, including males into the programmes may have a positive expressive function. It would show, in other words, that issues related to sexually transmitted infections are a common responsibility and, as such, they need to be shared. This move would, perhaps, contribute to normalize issues related with sexual life and HPV contagion.

Cost-effectiveness analysis cannot certainly incorporate such morally sensitive issues like the expressive role that a policy may have. It is not unreasonable though to propose that these considerations should also enter and inform the decisions of public health policy makers.

Nevertheless, there is still a strong intuition pointing towards a gender-based campaign. In fact, why should society spend more resources for similar outcomes only for reasons of equality between sexes? After all, as I have shown, employing resources properly is not sheer manifestation of greed. That public health programmes are economically efficient is important in that each resource allocated in one place is a resource that is taken away from somewhere else. For every need that is met there is one that is not. In this sense, one may rule out the option of massively targeting boys and girls. However, there is still the middle-way option of targeting around 50% of both genders. As the models presented show, that option may still be cost-effective although less than the option targeting girls only. The question thus remains:

should society go for the most cost-effective solution or issues of equity should be seriously taken into account?

The problem about equality, however, is even deeper than presented so far. Indeed, the issue is not only that adopting a gender-based strategy would perhaps have an undesirable expressive function with regards to the attribution of responsibility between genders. Rather, it has also to do with the fact that by setting up a gender-based campaign we are, more or less explicitly, overlooking the presence in our society of homosexual choices. As noticed above, the incidence of anal cancer in the group of men who have sex with men is higher than in the whole male population. The incidence of this cancer appears to be as high as it was the incidence of cervical cancer before society rightly took efforts to reduce it and save many women's lives. Thus if men will not be included in the campaigns there will be a group, homosexual males, which will be systematically excluded from the benefits of the preventive intervention. Surely, these cancers are, on aggregate, less burdensome for society as a whole and for this reason invisible to many. From the perspective of the individuals that will be affected by them, however, a justification in these terms may not be sufficient. People who will be affected in the future by anal cancer may complain that their interests were not taken into account in policy making because of their statistical irrelevance. Also in this case, hence, a gender-based campaign may exacerbate social divisions and foster sentiments of exclusion. The same, however, can be said about all those people that will develop HPV positive oropharyngeal cancers in the future. It must be noticed that while for cervical cancer society has set up massive screening campaigns such as PAP smears or HPV testing, the same cannot be said for other anogenital or

oropharyngeal cancers. As a matter of fact, at present there are no guidelines as to how such screening campaigns can be performed. Consequently, people belonging to high-risk categories for these cancers would not have any means other than the vaccine to ensure themselves a life free from the threat of such diseases. The possibility of preventing via immunization also these kinds of tumours becomes then an option that deserves serious attention.

As a counter, it could be claimed that one thing is to set a vaccination strategy and thus indicating the target group of the intervention, quite another to exclude people from the very possibility of profiting from it. Now that the vaccine has been proved to be effective in males too, men would have the opportunity to buy and obtain the jab thus preventing, if they wish, HPV-related morbidities. Of course, this is an opportunity that also homosexual people would have. Therefore, it can be claimed, there is nothing discriminatory in pursuing a gender-based campaign. However, this kind of argument may be misleading. As I mentioned above, the vaccine is more likely efficacious when people have not already come in contact with the virus. Thus, the ideal solution is to target preadolescents before sexual debut. On the other hand, it is reasonable to assume that prior to sexual debut, many pre-adolescents boys and girls do not yet have a clear idea about sexual identity. Nor we can realistically expect their parents to have such knowledge. However, some pre-adolescents will eventually choose not to pursue a heterosexual life. Those people would then be at risk of getting a cancer that we have the means to prevent. Given the age at which current strategies seek participation there seems to be no other way than extending the programmes to the male population too in order to meet also these interests. Therefore, if we want that

also these interests get protected the strategy of devising gender-neutral programmes becomes morally desirable.

Arguably, by failing to vaccinate males they will still be vectors, thus they could potentially infect non-immunized women and men. Vaccinating also boys, instead, would more effectively reduce the transmission of the virus both in heterosexual and homosexual populations. In the short or mid-term, this might result in herd immunity or, at least, in a drastic reduction in the presence of the virus. This would prove beneficial also for a number of people who could not take advantage of HPV immunization for several reasons. In the previous chapter we have seen that among the people who do not get immunized most belong to groups already disadvantaged from a socioeconomic perspective. Striving for herd immunity, and hence including boys into the programmes, can thus serve as a protection for those girls belonging to vulnerable groups.

These considerations have been provided to show that there are indeed good moral reasons to abandon gender-based programmes and include males into the campaigns. These reasons are even more important because, as it appears, the people that will be left out of the campaigns as they are currently performed are individuals coming from groups that already suffer forms of domination and disadvantage in our societies. People living in patterns of systematic disadvantage may feel excluded from the moral and political community thus creating a climate of resentment that can, in turn, foster social divisions. A policy that is as inclusive as possible, instead, shows how each and every individual is deserving of respect, at least shows this in the specific realm in which the policy intervenes. Showing that all the interests are taken into account with due respect, moreover, is a public manifestation that those

interests, although hold by a minority, have equal civic membership of those hold by a statistical majority. As suggested by Steven Epstein: "in relation to HPV, gay men remain incomplete biomedical citizens - benefiting, to some degree, from publicly funded research and from services provided at public clinics, but achieving only partial success in their demands that their health issues be placed on a par with those of other groups confronting comparable health threats" (Epstein 2010, 80). In this sense, providing herd immunity will not only be a public good but also a common good. That is, a good that arises from the public recognition of the moral worth of each interest and not merely a, still valuable, epidemiological phenomenon.

4. Concluding remarks

The three scenarios outlined above presented us with different options. All of them possess features that are morally attractive, at least at first approximation. The scenario A, the one in which 75% of girls and boys were vaccinated, is attractive because it can lead, if high coverage are then actually obtained, to a drastic reduction of the virus prevalence in a short term. Herd immunity provides benefits to all and, in this sense, is a public good worth pursuing. This scenario, however, despite attractive for the reasons explained, may come at a high opportunity cost and, perhaps, the resources employed for achieving that goal could be better employed to bring about other benefits in other medical and preventive contexts. The scenario C, the one that current policies pursue, promises less in terms of epidemiological benefits for all. Nonetheless, if large uptakes are obtained and maintained in the female population for a long time frame, it would bring about a drastic reduction in the incidence of cervical cancer cases and, possibly, also a decreased prevalence of

the virus in the population as a whole. Moreover, current cost-effectiveness models show that this scenario is the one with the most attractive cost-effectiveness profile among all those considered. Finally, the scenario B, more modestly, finds a middle ground between the two and suggests that with a 50% coverage between the two sexes herd effects would also accrue but in a slightly less cost-effective way. Clearly, all the models presented are hypothetical scenarios, telling us what would happen if certain conditions would be put in place. HPV vaccination campaigns, however, are still in their infancy and therefore all the options are still viable. What I let emerge in the discussion of the three models is the fact that all choices come not only with an opportunity cost, as defined in health economics, but with a moral cost too. Striving for the most cost-effective solution may be justified but this choice would not come without ethical implications that, I submit, should be taken seriously into account in deliberating about these issues. In particular, I have identified as morally dubious the expressive function that a choice of this kind may have. Insisting on a gender only, in other words, may foster the idea that issue regarding sexual health and prevention pertain exclusively to women as a group. A society that values issues of equality between genders - and democratic societies should value these issues – may want to take into account whether a gender-based programme is actually conveying this message. The importance of attending to the expressive function of a policy is particularly relevant in the context of HPV because the final 'users' of the intervention are individuals who are about to form their identities, even included their sexual identities. A gender-neutral policy could, if properly performed, promote the idea that men and women have equal responsibilities in avoiding the spread of sexually transmitted infections. An increased awareness of these issues in both

sexes, moreover, may turn out to be beneficial both for the health of individuals and, ultimately, for population health. Attending to the expressive function of a policy is certainly important but this is not the only reason that calls for a gender-neutral HPV vaccination campaign. Further support for the extension of those programmes to the male population too comes from a consideration of the actual health consequences a gender-based programme would have. If the data on the incidence of anal cancers in homosexual males are confirmed it would be disdainful to think of a campaign that reduces risk of HPV-associated cancers to all but for a group of individuals. In other words, if the aim of vaccination campaigns is to reduce risk of infections at the individual and population level, then identifying the category of at risk individuals on the base of gender alone is morally arbitrary. Some men may be more at risk than some women. If this were correct then excluding them from the very possibility of profiting from the intervention would be regretful. Clearly these interests are only so in a perspective sense. HPV vaccination, like any other immunization strategy, works only when the target group has not been exposed to the infective agent. In our case, boys and girls are targeted when they, perhaps, have not yet fully developed their sexual identity and, hence, cannot correctly anticipate their risk profile. Exactly for this reason, however, these perspective interests need to be taken more seriously into account and protected. Moreover, has I have shown, also the male population in general may benefit from the intervention both directly, in terms of reduction of males-specific HPV-associated morbidities, and indirectly, in terms of premature death of future wives and partners.

In this chapter I have shown that the possibility of striving for achieving herd effects is supported by strong moral reasons. What should we then conclude about the three scenarios presented above? Should then considerations pertaining cost-effectiveness or economic feasibility be left out from public decisions? I would argue that, clearly, they should not. As I have shown, in contexts of finite resources the effective allocation of goods is important, and it is so in a morally relevant way. The balancing is difficult and I have only shown my preference towards a more inclusive approach. Reasonable people may perhaps disagree. How could we then solve such a trade-off? Three solutions can be envisaged. First, we could devise methods to incorporate social values into cost-effectiveness analysis. These attempts are currently pursued by some scholars who are trying to 'empiricize' issues of equity by converting these concerns into data about public's distributive preferences (Menzel et al. 1999; Nord, Daniels, and Kamlet 2009). One could, hence, try to see if these approaches are able to tell us something in the HPV context. A second strategy would instead indicate a procedural approach to the issue by designing a fair deliberative process to cope with moral disagreement as it arises in this case. The 'accountability for reasonableness' approach developed by Daniels and Sabin is one of the most prominent attempts that go in this direction (Daniels and Sabin 2002). Instead, I would follow a third strategy and indicate, in the next chapter, that the present trade-off is better framed, and eventually solved, by specifying further the kinds of goods HPV policies should aim at promoting and distributing. To this last point I now turn.

Chapter 6: Case study conclusion. From resources to capabilities: A modest proposal for reframing HPV policies

1. Public health ethics between resources and outcomes

Having discussed the importance of health inequalities, and clarified that public health policies are, at least, required not to worsen those inequalities, it is now time to further specify what the relevant objects of distribution of social policies, in general, and public health policies, in particular should be. As exemplified in the first part of the thesis, the beneficence model encompasses concerns for distributive justice as an important part of what public health ethics is supposed to scrutinize. At first approximation, the idea that a fair distribution of the medical intervention itself should be the focus of ethical analysis tracks on the right intuition. A well-designed public health policy, indeed, should not exclude anyone from the benefits it provides on arbitrary basis like, for instance, morally dubious categories such as gender, ethnicity, or sexual preferences. A policy that would exclude, let us say, Afro-American individuals on the basis of their category belonging, would certainly be disgraceful. Further kinds of exclusion can, however, take place. Public policies can, sometimes, be unable to reach all people equally because of obstacles impeding full societal awareness of the policy. For instance, it has been noticed how less cultivated or economically disadvantaged people tend to take less advantage of medical services than people belonging to different social and cultural strata of society. As noticed above, different policies strategy can be put in place as to diminish the deleterious consequences of such impediments. Local

policy makers can, for instance, device information and educational campaigns specifically designed to reach particular communities. In other ways, public policies can exclude from their purview some publicly relevant interests because they are hold by a minority. The latter needs not being a form of intentional exclusion but, as Pettit calls it, a false negative danger inherent in public policies. A false negative occurs when a public policy, originally designed to track common shared interests, fails to identify and empower all the public stakeholders. This can be so, according to Pettit, either because there are publicly admissible reasons that have not surfaced in the public debate, or because not all feasible policy alternatives have been seriously taken into consideration (2004, 166). The discussion of the previous chapter is an example of a false negative. Gender-based HPV vaccination programmes, indeed, have so far failed to address the preventive needs that a gender-neutral immunization campaign would have also in a subset of the population. In the previous two chapters I have shown how these interests are morally important, and why there are strong moral reasons to take them into account properly. The way those interests can be taken into account, however, varies and, I argue, one way to meet them would consist in expanding our view on what are the morally relevant ends public health policies should strive for.

In the standard view in public health ethics – one that I have criticised for its limits, but also endorsed where appropriate - the main objects of distribution are medical resources. Clearly, one can have different intuitions or even theories as to how a distribution of those resources should take place. For instance, one can think that the distributive principle should be such to give equal resources to all who need them. Another, perhaps, would argue that the

best way to go, especially when those resources are scarce, is by giving priority to those who need it more. Still another one can support distributive principles that privilege those individuals that can profit more from this intervention. These problems are all too familiar in medical ethics, and are ready available in any major textbook in the field. What it is important for my work, however, is not to highlight their differences, but rather what are their similarities. And the main feature that all these approaches have in common is to conceive of medical resources as the right things to look at when thinking about issues of justice in medical settings. This way of understanding issues of distributive justice in bioethics is fine as far as it goes, but only as far as this. Below I will show in what sense resources should not be the main or only focus of our distributional concerns. Before doing that, however another set of problems that will also be important for answering the question informing this final chapter needs to be put forth

Suppose that we are asked to evaluate whether a given public health policy was successful and whether it was implemented in an ethical way. Suppose further that we are asked to do the job with the tools the beneficence model provides us with. To recall, the beneficence model conceives of ethical analysis of public health policies as an act of balancing among general moral considerations in case they conflict. To give an example, sometimes demands for increasing the effectiveness of the intervention may conflict with issues of autonomy – if people are forced to undergo a given intervention – or confidentiality – when the public health objective requires the state to collect and record personal information in disease registries. Otherwise stated, sometimes the general moral considerations that instantiates the goals of public health - producing

benefits, preventing harm, and maximizing utility – can come in conflict with other values like those listed above. In these cases, the beneficence model would tell us to put in place a balancing of the different values at play by means of the limiting conditions discussed in previous chapters. An analysis of the case would follow as to establish whether the achievements of public health goals warrants overriding values like liberty, confidentiality or justice (Childress et al. 2002, 172). As I have discussed throughout the first chapter, this is undoubtedly an important part of how an ethical analysis of public health policies should proceed.

Nevertheless, this analysis is silent on other respects. Indeed, the tools provided by the beneficence model are only relevant insofar as we are interested in the ethical analysis of the *means* of the policy, but they remain wanting as to their *ends*. So, if we take the first part of the question this paragraph began with – namely, how to assess whether a policy was successful - we should rely on something else, something residing outside the boundaries of the beneficence model. Most likely then, the only way we have to evaluate a given policy is to count on those measures that are typical of public health policy itself as, for instance, the extent to which a given intervention was able to maximize expected utility, both in epidemiological and economic terms. There are a plethora of health economics tools that have been devised as to perform this role. QALY and cost-effectiveness analysis are some of them, and I have provided an account of what they imply in our context in the previous chapter. To be sure, the use of these metrics does not go without critiques. For instance, some have raised concerns about the potential discriminatory effects that QALYs and cost-effectiveness analysis may have against the elderly (Harris

1987), or people with disabilities (Brock 2009). Even when these tools are subjected to ethical scrutiny, however, quite rarely the critiques are also based on a different positive conception of what public health policies should be aiming at. Again, ethical analysis is by and large concerned about the means of the intervention, but not about its ends. It is worth recalling, once more, that I am not criticizing this approach *tout court*. In many respects I think this is the way one should go, and in several parts of this work I endorsed and used this strategy. I would also argue, however, that if ends are not also taken into account by applied moral and political philosophers, then the only way that we are left with to assess the successfulness of a policy is in terms of its outcomes as stated by public health institutions.

In other words, if we are not able to spell out arguments as to what a policy should aim at, then we are left with the, still plausible, intuition that a policy is successful if it achieves its goals as defined by public health departments, and that it is ethical if the means adopted were acceptable according to previously established ethical standards. To make this point less abstract, if a public health policy is devised in order to reduce the incidence of, say, breast cancer, then the policy is successful when enough tumours at that site are prevented as a consequence of the intervention. In the case that has occupied large part of this work, moreover, one could be tempted to conclude that a given policy is successful if enough vaccines have been distributed so to achieve, perhaps in a cost-effective manner, population health goals. In both cases, moreover, the policies would be ethically justified if the least restrictive means were adopted and if the resources were fairly distributed. Examples of this kind can be produced at will and, I assume, everyone agrees that this is an

important feature of successful public health programmes that are also ethically justifiable.

This dynamics is certainly fine and, arguably, an important part of what public health ethics should be concerned about. However, these are not the only problems that deserve careful scrutiny. As anticipated in the second chapter, a complete ethical evaluation of public health policy should also elucidate what are the goods the policy is distributing. My aim is to show how the distribution of medical resources alone, is not the right focus for public health policy evaluation, and that their success should not be solely understood in terms of how those resources helped positively changing the epidemiological profile of a given disease.

2. Towards capabilities: the individual case

If not resources then, what else? In the following sections I want to elaborate on the weaknesses of these approaches by the means of the capability approach and show its relevance also with regards to HPV programmes. To fully understand the significance of the capability approach for discussion in the ethics of public health policies, some of its core ideas and the specific terminology need further specification (see also *infra* chapter 2).

Capability is the central notion of Sen's approach and can be defined as "a person ability to do valuable acts or reach valuable states of being; it represents the alternative combinations of things a person is able to do or be" (Sen 1993, 30). In other terms, capabilities are effective freedoms to achieve what an individual would consider valuable upon reflection. Capabilities, in this approach, need to be distinguished from functionings. While functionings are achieved outcomes, capabilities are the potential to achieve those outcomes if

one so wishes. To make one example, 'being healthy' is a kind of functioning people may or may not posses. In this respect, we can find adequate metrics, for instance relying on biomedical sciences, for claiming when one is healthy and when one is not. The same can be said about other functionings like 'being adequately nourished'. The problem that initially prompted Sen's analysis was the adequacy of functionings to describe individual well-being and, consequently, to use it as a metrics to assess public policies. Sen realizes that considering functionings to evaluate public policies and as measures of individual well-being is insufficient. In fact, he notices, people may have the same functioning and still have different levels of well-being.

In a now canonical example, Sen urges us to think about the differences existing between someone who is fasting for religious reasons and someone who is starving (1992, 52). Both have the same functioning (i.e. they are not well nourished), but they dramatically differ with respect to the capabilities they possess. One individual has the capability to be well nourished but he is choosing not to exercise it, while the other has not such capability. The upshot of this example is that an exclusive insistence on functionings, achieved outcomes, or resources people are provided with is insufficient as a sole guide for public policy. What triggers our moral sensitivity, and should also prompt adequate policy action, is what – beyond food - the starving person lacks: that is the capability to achieve one valuable desired functioning. Approaching the problem from a capability perspective enriches the landscape of moral evaluation and better accounts for human diversity. Saying this, however, does not amount to reject the importance resources may have in achieving valuable capabilities. In some instances, indeed, resources are necessary for expanding

capabilities. A person with motor disability, in other words, certainly needs a wheelchair to move around with expanded independence. Nevertheless, what makes resources functional to the scope depends on what are the factors that would allow individuals to exploit those resources properly. For example, we can provide two people with similar bikes, and yet what we achieve may not be the same result. One person may convert the resource into a valuable outcome, for instance if she was taught how to drive a bike, while another may not be able to do that, for example because she is physically impaired or because her city is not provided with adequate cycling lanes (Robeyns 2011, 13). In the capability approach, the latter are called 'conversion factors' and can be of various nature. They can be 'personal', thus depending on the particular natural endowment of the person under consideration. They can be 'social', thus depending on the kind of society one lives in, whether there are in place discriminatory practice, strong social hierarchies, or power relations related to gender, class, or ethnicity. Finally, they can also be environmental, having thus to do with the physical environment a person happens to live in (Robeyns 2005, 99). The problem of conversion factors is also apparent in the case of HPV policies. Provided that giving the vaccination to girls before they initiate sexual activity really protects them against the relevant HPV types, it alone does not permit to judge how much their capabilities have been actually enhanced. We can imagine different situations all related to the different conversion factors different individuals have at their disposal.

Mary, for instance, comes from an affluent neighbourhood. Her parents provide her with all the material and cultural tools for a correct development. After consulting each other, the parents decide to immunise Mary against HPV

because they think she could profit immensely from the vaccine. Arguably, these parents will explain to Mary the benefits of the vaccine, what it means for her future sexual encounters, and what kind of preventive measures she will need to take still for avoiding sexually transmitted infections. Moreover, Mary's parents could also teach to her, when they feel appropriate and according to their educational style, that the vaccine she has had when she was 12 only gave her a shield against HPV infection. Still, she needs to perform regularly, and when appropriate, the PAP test for screening cervical abnormalities that may lead to the development of cervical cancer. The girl of our example is an individual provided with the right capability to health, at least in the context of HPV and other sexually transmitted infections. After having been provided with the capability, Mary can decide whether to exercise it or not. In other words, Mary has been provided not only with a resource (i.e. vaccine) and the relative functioning (i.e. immunity against HPV) but also of the adequate capability to exploit a whole set of health-related resources, should she decide to do so.

Let us imagine now another girl and call her Francine. Francine's parents do not take much care of her. This may be so for different reasons. She may come from a poor background and her parents have simply no time to consider all her medical needs. They are not necessarily bad parents, but probably the lack the appropriate knowledge to give to her an adequate preventive education. Despite this fact, Francine's parents receive a letter from the local clinic suggesting their daughter may be immunized against HPV. They may decide that vaccination, after all, is good and let her to take the jab. The jab, at least in this example, is not accompanied by any kind of information about its significance, and what further steps need to be taken for correct preventive

practice. Francine would not know what HPV is, what its link with cervical cancer, and what are the other preventive strategies she would need to perform in the future. Clearly, our girl is now protected from HPV, and she is objectively protected from the most dangerous strains. Francine, however, does not have the capability for fully take advantage of the opportunity. Francine may eventually come to know anyway of the necessity of undergoing PAP smears once she becomes sexually active, or she may not. What it is important for the sake of this argument is that Francine has not been provided with the capability, but only with the functioning.

Margaret, instead, comes from a middle class, warmly religious family. Margaret's parents provide her with all she needs, and take care of her adequately. Margaret's parents receive a letter of invitation from the local clinic offering HPV immunization. They read carefully the information, and decide that they will not give the vaccine to their daughter. They decide so maybe because they read that there are still uncertainties about the duration of the immunity, or probably because they have heard that the PAP test will need to be performed anyway. Perhaps they do so because they would prefer to introduce Margaret to sexual education gradually and according to their values, which include abstinence before marriage. They sincerely do not believe that the vaccine is an incentive for sexual promiscuity, but for the reasons explained they decide not to give her the jab. However, they will certainly provide her with sexual education and inform her about the risks of unsafe sex. With regards to cervical cancer, moreover, they will explain the risks and the importance of performing screenings for a correct preventive practice. Margaret, differently from Mary and Francine, has not been provided with the

functioning. Therefore, she is in a sense more at risk of being infected from HPV. Margaret's capability to health, however, has been expanded and she would then decide whether to exercise it or not so to achieve the functionings she considers valuable.

Sophie comes from the outskirts of a big city. She is 13 and she is the oldest of four children. She has no father and her mom, who shoulders alone the burden of raising the family, has to commute more than 2 hours every day to work. Sophie's mom cannot afford baby sitting, and so it is Sophie that has to take care of the three little kids every afternoon. Sophie is more mature of many of her peers at school; indeed she has more responsibilities than other girls and boys at her age. Sophie thinks she is already a woman and, perhaps for this reason, she has already had her sexual debut. Sophie's mom has never performed cervical cancer screening and she is not aware of HPV and its risks. As a consequence of that, Sophie will not get the vaccine nor anyone will explain to her what is HPV, what is cervical cancer and, perhaps more importantly, what it means to conduct a responsible sexual life if one wants to avoid sexually transmitted infections and diseases. Sophie - who will perhaps come to know these things through magazines or peers - has not been provided with the functioning and her capability has not been expanded. In a sense, she is also the one more at risk of infection among the four girls.

Then we have Bob. We do not know anything in particular about him. He may come from an affluent background or not. His parents may provide him with all that it is necessary for the full development of his capacities or they may not. What we know about Bob, however, is that nobody has ever told him about HPV, what are the risks for males, how men are involved in the transmission of

the virus, and why it is important to conduct a responsible sexual life as a matter of personal prevention and for the other-regarding outcomes his behaviour may cause. Bob, perhaps, attends a school in which girls are routinely immunized against HPV. He sees his girl classmates queuing out of the school nurse's office awaiting immunization. Some of them are scared by needles others just do not care. Some of Bob's boy classmates make fun of the scared girls, others just pass by and watch without understanding what is going on there. Bob one day will become sexually active, he will most likely have a heterosexual identity but perhaps he won't. He will very likely be infected with HPV and, in turn, he will infect his sexual partners. With a high likelihood he will not develop any HPV-associated cancer, or perhaps he will. This will depend, clearly, on a complex interaction of factors. Complexities notwithstanding, however, we know that Bob has been provided neither with the resource nor with the capability. Therefore, he has been prevented from developing an awareness of his role as a vector in the chain of infections.

How to evaluate these imaginary, yet realistic, examples in terms of comparative advantages given to the individuals who were asked to undergo the intervention? The case of Bob will become important below where I will explain why a focus on capability is also functional to shed more lights on the issues of gender equity discussed in the previous chapter. For the moment, however, let us concentrate on the cases of Mary, Francine, Margaret and Sophie for the sake of simplicity. If we look at resources and achieved functionings alone, then it is easy to establish who is better off and who is worse off in the examples provided. Mary and Francine both got the vaccine and so they have achieved, thanks to the resource provided, equal functioning

(i.e. they are immune against HPV). Margaret and Sophie instead, since they were not provided with the resource, are both lacking the relevant functioning.

By looking at resources and achieved functioning alone we can readily establish a ranking of the cases at hand. The latter would look as follows:

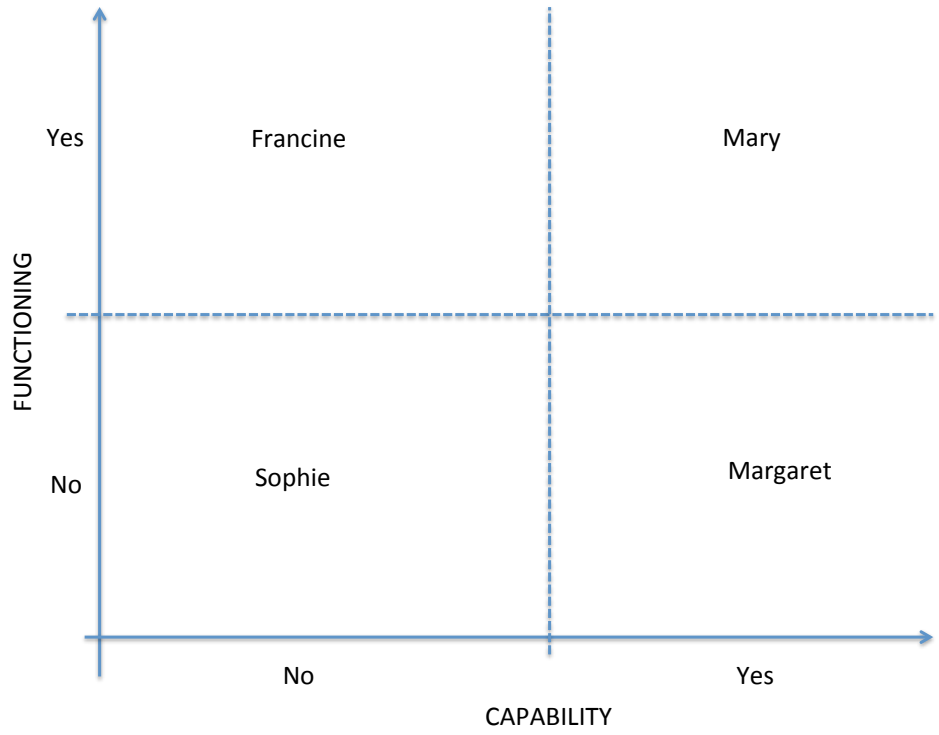
	FUNCTIONING
YES	MARY - FRANCINE
NO	MARGARET - SOPHIE

Table 5. Ranking of the individuals with regards to achieved functioning

In other words, functioning in this case is a binary condition: either you have it or not. In this sense, Mary and Francine are better off after the intervention, whereas Margaret and Sophie's conditions have not improved. If we look at functionings only we have no way to tell whether there are differences among the four cases.

If we instead enlarge our view to capabilities our evaluative exercise is enriched and we are permitted to assess the situation differently. If we look at

capabilities together with functioning, indeed, we can make more fine-grained analysis and distinguish among the cases. From the capability perspective, indeed, Margaret and Mary have had their capabilities expanded, whereas Francine, although she has been immunized, is in a position of relative disadvantage. She will probably not be able to understand what she can do and what she cannot do with the resource she was provided with. HPV vaccination, in fact, is only a bit of the whole set of measures that can lead to improved functioning with respect to cancer and sexually transmitted diseases. In the same way Sophie, although she and her family were not interfered by the gender-based campaign, did not have her capability to health expanded. The graph below summarizes in what sense a ranking of individual advantages based only on achieved functioning misses to take into account diversities existing among the cases presented.



Graph 4. Individuals' position in a bi-dimensional space

As we can see the introduction of capability adds a further dimension of analysis, and permits us to make more specific considerations about the cases at hand. We can imagine that, prior to the educational and preventive interventions, all the individuals of our example were in the position of Sophie. They had no achieved functioning with respect to HPV and related cancers, or the capability to achieve those functionings. After these interventions – directed by the families - we see that Mary has moved from the left-lower to the right-upper quadrant of the graph. Now Mary is effectively protected from HPV (at least the types covered by the vaccine), but she is also able – since we are assuming she received an adequate preventive education about sexual health – to achieve a broader set of related functionings if she so wishes. Indeed, the capability she has been provided with would allow Mary to protect herself against other sexually transmitted infections, unwanted pregnancies, or cervical cancer caused by other HPV types, if she so wishes. Francine, instead, has moved to the left-upper quadrant of the graph. Now she possesses full functioning against HPV (i.e. she is immunized) but – since we are assuming she was not provided with the capability – she is not able to protect herself against other sexually transmitted diseases. In this sense, the package of functionings that is open to her is smaller than Mary's. Margaret – the girl that in our example was fully educated but not immunized – possesses the capability to function, but not the functioning itself (i.e. immunization). This marks a difference between her and Francine and, in a sense, we can say that the latter is advantaged with respect to the other. Nevertheless Margaret, like Mary, possesses a capability that would permit her – at least in our example – to achieve a larger set of functionings than Francine, if she so wishes. As I said, she could autonomously decide what risks to take, how to take them, and what kind

of protection she desires. Sophie, the last girl of the example, is the only one who has not moved from the left-lower quadrant of the paragraph: her capability has not been expanded, nor she improved in terms of functioning. She is the worst off in our graph. Sophie, it needs to be recalled, was also the worst off in the ranking of individual advantages taking only achieved functioning into account. In that context, however, the differences between Sophie and Margaret were invisible. To understand this point better let us recall Sen's example concerning the difference between the man who is fasting and the one who is starving and see how it maps onto our distinctions. Margaret (and her family) is, all other things being equal, in the position of the man who fasts. Sophie (and her mom) has not the capability to choose whether to fast or not. Therefore, she is metaphorically starving. The one-dimensional character of the 'functionings model' flattens the differences, also those that appear to be morally relevant, like the one between who fasts and who starves.

From an individual perspective, to conclude, we can say that what fosters our moral scrutiny more is Sophie's case rather than Margaret's. In this sense, I would argue, everyone would prefer to be – all other things being equal – in the position of Margaret rather than in the position of Sophie. This simple yet powerful shift in perception, I would moreover argue, is made possible by expanding our evaluative gaze from functionings to capabilities. If the arguments presented are correct, hence, capabilities are morally important goods to distribute along with functionings.

What said so far applies at the individual level. It remains, however, to assess what the capability perspective tells us at the population level. To the analysis of this next point I now turn.

3. HPV vaccination policies and capabilities: the population case

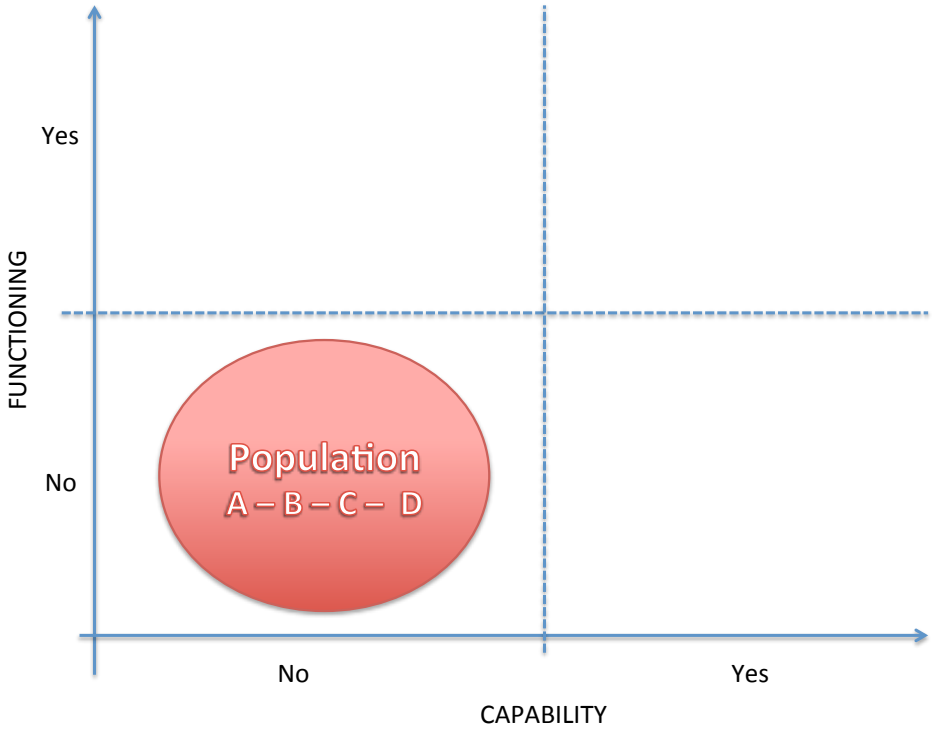
In the previous section I have assessed in what sense the capability approach, applied to the HPV case, enlarges the scope of our evaluative exercises. The capability approach adds up a second interpretative dimension to an evaluation based only on the functionings achieved after resources have been distributed. The comparisons made, it must be admitted, were based on fictional examples. Real life situations are certainly more nuanced and it is not easy to make clear-cut distinctions. For instance, we cannot always claim in a straightforward manner whether actual Margarets are always better than Francines, or vice versa. At the same time, however, reflecting on what people can do and be certainly broadens the thickness of our observations and, I would argue, also of our moral sensitivity. What we think is morally relevant concerning Sophie is not only that she lacks the functioning but also, and perhaps more, that she has not even the same capability of Margaret.

In a similar manner, we could use the capability approach to assess how populations are faring with respect to one another or establishing, accordingly, how we would like a given population to improve its present conditions.

As noticed above, if we evaluate a policy only with respect to the functioning it provides, then it is readily understandable who is faring well and who is not (at least according to the policy objectives themselves). Indeed, this calculation can be done by simply summing up the numbers of immunized individuals and the numbers of the individuals who are still susceptible to the infection. Accordingly, those who are immunized are faring well whereas the others are not. Clearly - and more importantly given the population focus of this section - if

the number of immunized individuals is high enough as to sustain population health goals established by public health departments then we can also claim that the policy was successful. If to this perspective, however, we add capabilities as a further element of assessment, then also in the population case different scenarios would open up to our scrutiny. Otherwise stated, capabilities can tell us how to better evaluate current situations as well as suggesting what ought to be distributed along with functionings.

Suppose, for the moment, that we had measures to calculate, in a more or less precise manner, capabilities along with functionings. Suppose further that we want to assess how four HPV policies fared with respect to both the dimensions some years after they were initiated. We would observe – like in the individual case – how the relevant populations (call them A, B, C, and D) improved their baselines after the introduction of the intervention. In the graph below we see the positions of $population_{A\text{-}B\text{-}C\text{-}D}$ with respect to functioning and capability before the campaigns start, let us call it $time_0$.



Graph 5. Populations' positions at $time_0$

After the campaigns start $population_{A\text{-}B\text{-}C\text{-}D}$ will move somewhat. Let us think first at the extreme situations.

At $time_0$ the HPV campaign for $population_A$ starts. It is a very bad campaign. The public health department in that area does not have enough funds for buying all the vaccines, nor the professional expertise to devise an efficient plan of action for its delivery. Moreover, no educational campaign is made so to inform the public about the possibility of the intervention or to make people aware of the connections between HPV and cancer. As a consequence, at $time_1$ $population_A$ remains still in the left-lower quadrant of the graph. No one was endowed either with the functioning or the capability. We would say, in this case, that the campaign was certainly unsuccessful.

In the case of $population_B$, instead, we assist to a quick vaccination campaign strongly endorsed by the State and the local public health authorities. The

stated objective is to perform a campaign as efficient as possible and to achieve significant population goals in the short-term. Perhaps the campaign is mandatory, allowing very little space for individual exemptions. In any case, the primary aim of the campaign is to maximize functioning and no educational initiatives are devised as to increase awareness of HPV as a cancer risk factor in the population. At $time_1$, hence, $population_B$ is fully functioning (i.e. the vast majority of the individuals are immunized) but all individuals within the population lack the correspondent capabilities. According to functioning alone, the HPV policy for $population_B$ was certainly successful.

The case of $population_C$ is a peculiar one. The state, like in the previous situation, promotes a mass vaccination campaign against HPV. The incidence of cervical cancer in that area is consistent, but not too high. The public health department, therefore, launches a robust educational campaign aimed at achieving vast awareness about HPV, cervical cancer, and other sexually transmitted infections. It moreover offers the possibility to prevent HPV and associated diseases by the available preventive tools (i.e. vaccination and PAP test). The educational campaign is addressed to families, their pre-adolescents children, nurses, physicians and all professional operators in public health. In the context of these information campaigns the HPV vaccine is offered to all those who want to take the opportunity and who can benefit from it. For some reason, at $time_1$ almost nobody gets immunized, but the vast majority of the population understood the risks and will modulate its behaviours accordingly. As a consequence, at $time_1$ $population_c$ is faring badly in terms of HPV-specific functioning (i.e. few people are immunized) but, we suppose, it is faring well in terms of capabilities to function.

The last extreme case in our model is that of $population_D$. $Population_D$ is in many respects similar to $population_C$. Both populations have more or less the same demographic and age structure, the patterns of sexual behaviours are alike and so are the rates of HPV infections and related cancers. Similar, in our model, are also the campaigns enacted by the respective public health departments. Also in the case of $population_D$, that is, the offer of the vaccine is accompanied by intensive educational campaigns to the population. One relevant difference exists, however, between $population_D$ and $population_C$. At $time_1$, indeed, almost all individuals within $population_D$, take advantage of the vaccination offer and immunize themselves against HPV. $Population_D$ possesses now the functioning against HPV and all individuals are endowed with relevant capabilities.

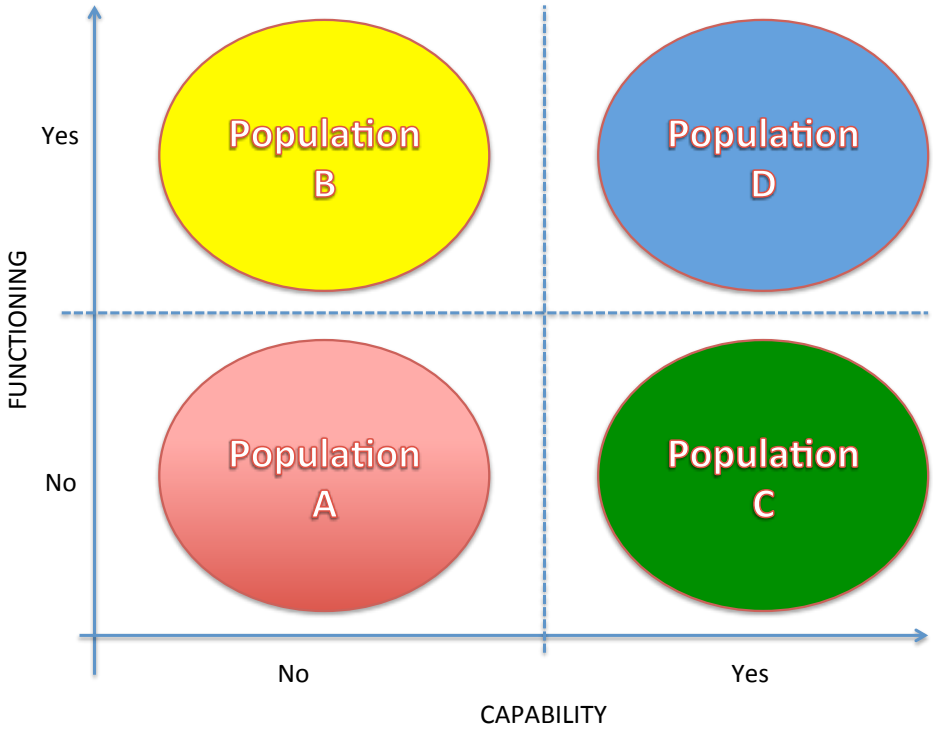
It should be clear, by now, that there are relevant differences among the four extreme cases presented. For the sake of completeness, however, let us see how would we evaluate them if we were only concerned about achieved functionings. They would rank as follows:

	FUNCTIONING
YES	$POPULATION_B$ - $POPULATION_D$
NO	$POPULATION_A$ - $POPULATION_C$

Table 6. Populations' ranking according to achieved functioning

As we saw above in the analysis of the individual cases, a look only at functioning does not allow us to appreciate properly what are the differences among the cases. In other words, our evaluative gaze is compressed into one single dimension: some people are immunized whereas others are not; some systems are efficient whereas others are not.

In parallel with the individual case, however, taking into account capabilities into the analysis enriches our perspective and permits us to assess the differences among the cases and see whether they are morally significant. Adding capabilities to considerations on functioning allows us to look at things in two dimensions. The graph below provides us with a visual representation of how $population_{A\text{-}B\text{-}C\text{-}D}$ are positioned with respect to both functioning and capabilities at $time_1$:



Graph 6: Populations (A-B-C-D) at time$_1$

The new dimension offered by a concern with capability permits us to make more detailed comparisons among the populations.

Population$_A$ and population$_C$, for instance, have both the same level of functioning – namely, absence of it. The latter, however, has been endowed with capabilities – i.e. the population has been reached by an effective educational campaign – and therefore its citizens have now at their disposal the possibility to choose, if they want, what actual functioning to pick up from the set of capabilities they now have. For instance, citizens of population$_C$ can decide – in our model – what kind of sexual behaviour to adopt, whether to take advantage of other preventive services, and so forth. By adding the capability dimension, hence, we can appreciate that population$_A$ is faring worse than population$_C$. This distinction would have been fairly invisible if we were concentrating on functionings alone.

Population$_C$, to continue with our comparison, is certainly different from population$_B$. The latter has moved, after the intervention, from the left-lower to the left-upper quadrant of the graph. In this sense, population$_B$ is now provided with the functioning but not with the capability. Who is better off between the two populations? In a sense - in parallel with the considerations made in the context of the individual case – population$_B$ is objectively more protected from HPV 16 and 18 than population$_C$. Nevertheless, population$_C$ has still the potential to achieve the same functioning with regards to cervical cancer than population$_B$. Moreover, individuals in population$_C$ have at their disposal a capability that would allow them to achieve a larger set of functionings. In other words, they can now decide what kind of preventive practices to adopt and what kind of risks to take in a conscious manner. While I was discussing the analogous individual case – i.e. Francine and Margaret – I said that there is a sense in which we are not able to assess who is better off between the two. Perhaps, this consideration holds also in this case. In at least some respects, however, population$_B$ is worse off than population$_C$. In the former, indeed, we have assumed that individuals were not free to choose the level of their functionings. That level, indeed, was imposed from above. In this regard, population$_B$ possesses only the relevant functioning of immunization, but it is not fully free to achieve other similar functionings related to sexual health in an independent manner, even included non HPV 16 and 18 related cancers.

This consideration marks also the difference existing between population$_B$ and population$_D$. In population$_D$, indeed, the level of functioning achieved is the result of free choices made by individuals who were first provided with the capability to function. In this respect, population$_D$ can also achieve other

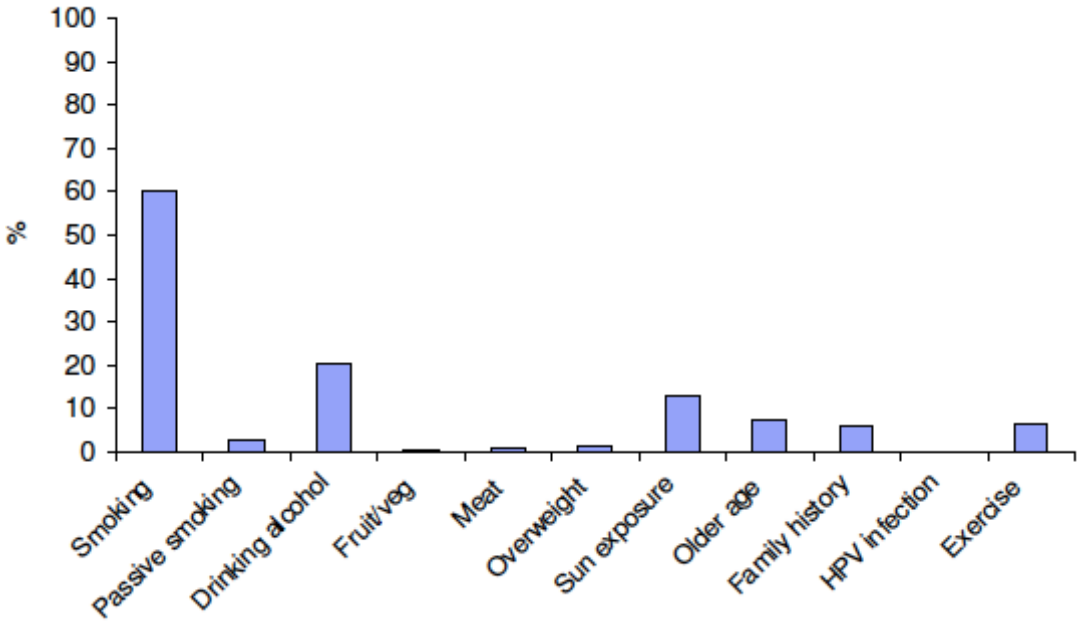
valuable functionings without the need of coercive measures. Population$_C$ and population$_D$ are – at least in the model – effectively free to reason responsibly about the value to attribute to sexual health and prevention and to act accordingly. Moreover, the capability they now possess is fully theirs like the functioning they have or have not. Differently from functioning, moreover, capabilities can be transmitted to the future generations through dialogue and education, while functioning (at least in the form of immunity) cannot. We can thus imagine that individuals in population$_D$ will be in the future more likely to provide also their daughters with the capability to health and an understanding of what are the preventive steps one needs to take to achieve functioning.

So far I have only discussed four fictional scenarios. In reality there will be no population with the exact features of those presented in the model. More likely, individuals in various populations will be distributed throughout the graph, with some density in each quadrant. Some people will be positioned in the right-upper quadrant, some others will move to the right lower and so forth. If we accept, however, that conditions such as those in the left-lower quadrant of the graph (no capability and no functioning) are morally unsatisfactory, and situations like those in the left-upper quadrant are, at least not optimal, then ideal distributions would be those that allow moving as many individuals as possible to the right part of the graph. If these arguments are valid, therefore, we should conceive of capabilities as 'objects' to be distributed along with functionings and, perhaps, as a further measure of success of HPV public health policies. Clearly, the optimal solution, namely the whole population moving to the right-upper quadrant, will be difficult to achieve. It, however, can function as a compass for directing policy action.

In the present and in the previous sections I have shown that enlarging our focus to capabilities will enrich ethical analysis and, if my arguments are correct, also the kinds of aims public health policies should have. Nevertheless, before proceeding to assess how capabilities can be distributed in our case, some complications need acknowledging with regards to evaluation of policies at a given time point.

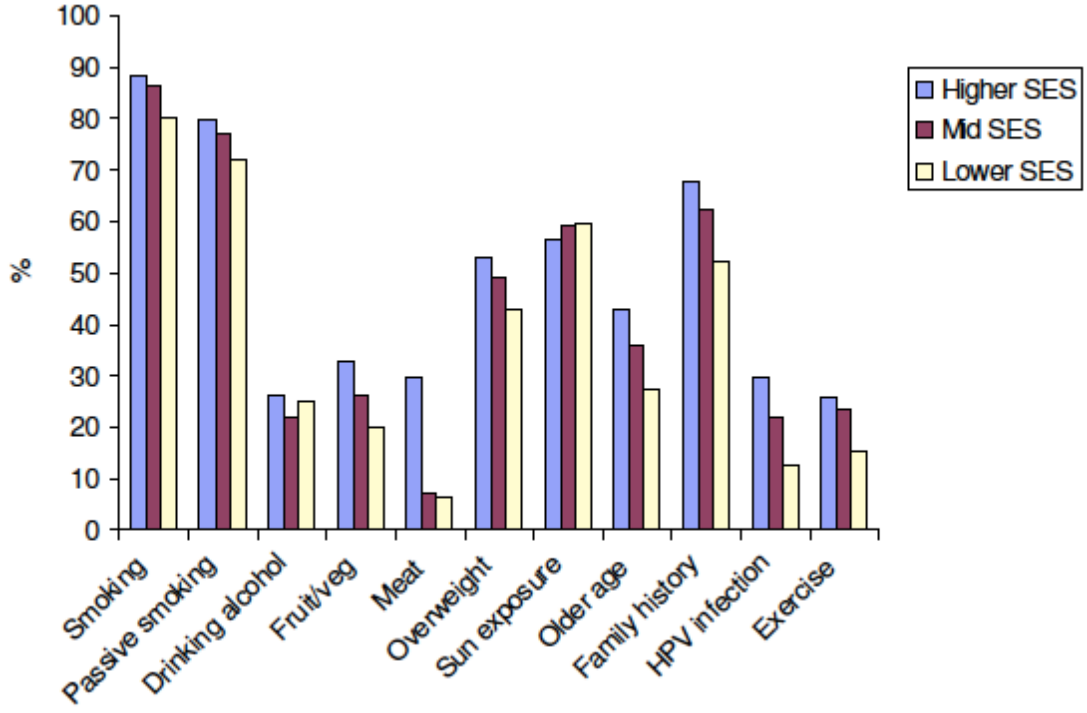
In the model I have presented, capability is conceived, like functioning, as a discrete condition: either you have it or not. In actual cases, instead, capability is better conceived as a continuum rather than a yes or no condition. In other words, one individual's capability can be more expanded than that of another, and this along a gradient of personal variations. Given this variation, hence, one could ask where we should set the threshold of achieved capability in the graph. If we set it too much to the right, then very few people will have an acceptable level of capability, and so no policy could possibly be ethically acceptable. If we set it too much to the left, instead, there will be virtually no difference between a functioning-based evaluation method and a capability-based one. How to set this threshold, hence, is not easy task and I am not aware of anyone who has ever managed, or even attempted, to set it precisely. For instance Martha Nussbaum (2006), when she discusses the importance of capabilities in general, adds only that every individual needs to have a sufficient level of them. This threshold, hence, is not easily established in general, nor the situation is less complex in the specific case of HPV. Despite difficulties, however, I would say that we should not be too much worried; at least not in the context of my proposal. Indeed, no matter where we set the threshold, we can agree that a necessary element for achieving capability is – at a minimum – awareness of the

very existence of the problem and what it implies. If we look at this primary, necessary feature, we observe that general awareness at a population level of HPV as a cancer risk factor is lacking. For instance, a report published in 2009 by the *University College of London* provides the results from two national surveys conducted in the UK employing a sociological tool for assessing current levels of cancer awareness on a national basis. Among other things, the survey shows that public recollection of HPV infection, as a risk factor for cancer, is nearly absent (see graph below). That is, almost nobody, when asked to recall risk factors for cancer, listed HPV as one of them.



Graph 7. Recollection of risk factors in UK. Drawn from (University College London 2009, 24)

Moreover, when asked to recognize cancer risk factors within a list of candidates, respondents showed a general poor level of awareness of HPV infection. Such awareness was, additionally, clustered along the socioeconomic spectrum, as we see further in the graph below.



Graph 8. Recognition of cancer risk factors by SES in UK. Drawn by: (University College London 2009, 23)

These data provide support to the idea that, at least at the population level, we are currently far from achieving a sufficient degree of HPV-related health capabilities. If the problem of how to formally evaluate policy performance also from the capability perspective is not yet solved, it remains, however, the inspirational focus of capabilities and the need to conceive of them as a good of distribution worth expanding along with functionings.

4. Distributing gender-neutral capabilities

If we admit that the focus of our moral concerns with respect to public health policy should be enlarged not only to the level of functioning they distribute, but also the capabilities they provide and to whom, then also our gaze with regards to HPV policies should change. In this sense, the aim of HPV policies should be that of moving away from the left-lower quadrant of the graph, the most morally worrisome one, as many Sophies as possible. In other words, the

inspirational goal of HPV public policies should be – at a minimum - that of expanding capabilities for all. The data provided at the end of the previous section tell us that there is still something to do to achieve this goal. How could then a policy provide the relevant conversion factors to all Sophies? In the fictional scenario provided in this chapter, Sophie comes from a particularly disadvantaged background. This feature, however, is not only the outcome of mere imagination, but it is also supported by the data presented in the course of the fourth chapter, where I have shown that reasons for non vaccination depend also on the network of familial preventive practices girls find themselves into (i.e. the girl's likelihood to be exposed to relevant preventive practices depends on the mother's disposition towards those practices). It is not my intention here to make a full proposal for policy implementation but, as the title of this chapter reads, only a modest one. In particular, I would like to sketch what a policy framed in terms of capability would imply and why, after this perspective is endorsed, it would shed new lights also on the trade-off that has occupied the previous chapter. To recall: individual choice vs. population health; individual choice vs. justice; justice vs. efficiency.

A reasonable way to start in the attempt to provide some features of capability-based policy options is by rehearsing how current policy models fare under this new lens. Let us start from the mandatory model as performed in the US. I have already provided independent arguments as to why a mandatory model is not ethically justifiable in the HPV context. Do considerations about capabilities change my evaluation of that model? I would say they do not, at least as they are currently performed. In the mandatory model, indeed, we see that the central objective of the policy is to achieve functioning by conditioning school entrance

upon vaccination. As I have shown, information about HPV and its links with cancer were provided to objectors after reviewing not better-specified material describing those links. Therefore, the main objective of those policies is to create a population like B above and not one like D. In other terms, the mandatory US models starts from functionings and resources rather than with capabilities and, only later, functionings. What about, instead, the voluntary models? Those cases, as we saw, were heterogeneous but, to simplify, we can say that the voluntary models in US and in Italy, although to different extents, do not ensure that most individuals move, at least, to the right-lower quadrant of the graph. In the UK case, instead, we see that many individuals (see *infra*: chapter 4) achieve functioning (i.e. they get the vaccine). Do these individuals also have their capabilities expanded? The evening information sessions with parents seem to suggest that in a sense, they do. More informed parents, we may speculate, are more likely to educate their daughters properly so to allow them to leave the left-lower quadrant of the graph. The school-based model hence allows me to provide a general policy recommendation: schools are suitable places where to perform capability-based HPV policies.

As I have shown throughout this chapter, what makes Sophies disadvantaged with respect to vaccination and cervical cancer is not simply the fact that they are not willing to take the vaccine, but that they lack relevant conversion factors to expand their capabilities and achieve valuable functionings, if they so wish. Schools, in this respect, can function as places where relevant conversion factors are provided. School in our societies is the institution traditionally devoted to the distribution of a host of capabilities and opportunities to all its future citizens. Moreover, schools are among those few institutional places

where individuals from the whole socioeconomic spectrum convene. In this sense, it can be also a place in which educational tools regarding disease prevention and sexual health can be conveyed, and as many Sophies as possible be reached.

Clearly, I am not necessarily suggesting that the school should be also the place of vaccine administration, but it can certainly be the place in which relevant capabilities are distributed, both to parents and their children. Following the example of the UK, one can imagine that educational sessions are provided in afternoon meetings to parents. These meetings could be conceived as an opportunity for groups of parents to encounter paediatricians explaining HPV as a sexually transmitted infection, its link with cancer, what are the steps that need to be taken for correct prevention, and discuss the opportunity of vaccination. Moreover, in this setting one can imagine parents participating in deliberations about the ways in which their sons and daughters will be exposed to the information.

If we conceive of capabilities as the 'object' of distribution, rather than resources and functioning alone, then it becomes feasible also to provide these capabilities to boys. In section 2 of this chapter I have illustrated the case of Bob. Bob, like Sophie, is not provided by current policies neither with the capability to function or with the functioning itself. This aspect is morally worrisome in that it may foster – as I said in the previous chapter – the idea that responsibilities as to issues pertaining to sexual prevention are a female only problem. The deficiency in current policies, I argue, derives from a focus too much flattened on issues of resources and achieved functionings alone. As I have shown in the previous chapter, we have strong moral reasons in the HPV

context for choosing a policy plan that, despite not optimal from an economic perspective, would include also the male population. Nevertheless, even if my arguments are not accepted as sufficient for expanding the target group of vaccination itself, moral reasons still support the necessity of expanding boys' capabilities. Providing the capability to boys and their families too, indeed, is important to allow them to understand better their role as potential victims and vectors of the infections. This understanding may prove important also in terms of future functionings of the population as a whole, in terms of a population that is aware of the risks it faces. Last October, ACIP recommended the HPV vaccine also for boys. Although this recommendation has not been ratified yet, we can suppose it will be soon, and that other countries will also consider this option. One may think that such a recommendation jeopardizes my proposal, but I think it does not. Indeed, recommendations in ACIP language means only that paediatricians are asked to propose the intervention in a routine manner. I have already shown, in chapter four, that this strategy runs the risk not to bring about good results both in terms of functionings and, with the language of the present chapter, in terms of capabilities. Therefore, my suggestion would build upon also this kind of extension. In the last section of the previous chapter, moreover, I have alluded to the fact that by concentrating on capabilities as a further 'object' of distribution would shed new light on the trade-off between justice in terms of gender equity and efficiency in terms of cost-effectiveness. In that chapter I have provided moral grounds to tell that the scenario that is more inclusive while being not the most cost-effective alternative, is the one that should be preferred. In this respect, that still is the way I would solve the trade-off. No matter what of the three scenarios presented in that chapter public health authorities would end up choosing, the distribution of capabilities in a

gender neutral manner remains essential and comes at no cost if not a good deal of social and political imaginary.

5. Concluding remarks

I have only sketched the place in which the distribution of capabilities could occur. Arguably, a detailed description of how the provision of capabilities should take place goes beyond my specific competences and, in any case, would require another work. Nevertheless, I have shown that by focusing on capabilities rather than achieved functionings alone permits us to understand what are those conditions that are morally puzzling and, consequently, what are the policy priorities that need to be addressed if this perspective is endorsed. The ways in which a school-based programme can be performed varies, clearly, from context to context. It requires, indeed, a host of institutional and professional cooperations that vary from system to system. My general analysis, in this respect, cannot give precise details about what to do in specific policy contexts. Nevertheless the idea of expanding capabilities prompts an overall framework that seems able to take into account so far neglected dimensions of systematic disadvantage.

Conclusions

The main focus of this work has been the exploration of ethically relevant issues in the context of a case study. Licensed between 2006 and 2007 by several regulatory agencies, and promptly endorsed by several public health systems in developed countries, the HPV vaccines reopened, in both old and novel forms, concerns that have accompanied the institution of mass immunization campaigns throughout their successful, yet contested, history. HPV vaccination, perhaps more than other public health measures, embodies much of the most significant ethical dilemmas that public health has to face in our times. With three shots to be administered over six month, HPV vaccines confers immunity against those sexually transmitted infections that are now known to be the necessary, still not sufficient, cause of cervical cancer. Like any other vaccine against a contagious agent, HPV vaccines would confer maximum benefits if administered on a population scale so to decrease the prevalence of the virus and, consequently, the incidence of related morbidities. The way for its full benefits to become reality, however, is not devoid of ethical complexities. What are the right means for maximizing population benefits while respecting individual choice, how to do this in the face of existing inequalities with regards to cervical cancer, and in a way that also preserves economic efficiency, are some of the questions comprising what I called the ethical dimensions of HPV vaccination policies. Policy proposals to make vaccination mandatory for preadolescent girls entering sixth grade in the US, and the gender-based nature of how current policies deal with such a sexually transmitted infection, render HPV vaccination even more problematic from an ethics perspective.

In order to make my exploration analytically robust I have structured this work in two parts: a first part dedicated to the provision of a suitable theoretical background for the analysis of the case study; and a second part dedicated to the ethical analysis of the case itself.

In the first chapter, I started from the analysis of the received view in public health ethics, what I called the beneficence model of public health ethics. The beneficence model seeks to establish those conditions that should regulate the ethical implementation of public health policies. It recognizes that population health is important but, nonetheless, it also acknowledges that sometimes public health activities may contrast with other important values like individual freedom, understood in this model mostly in its canonical non-interference form. In this respect, the beneficence model provides us with a number of limiting conditions that should ensure that the invasion of the individual sphere by public health institutions is kept to a minimum. In the same chapter I have, then, contrasted the beneficence model, that provides us with a revised liberal framework suitable for public health, with intuitions coming from another school in political philosophy, namely republicanism. I have noticed that republicanism rightly tells us that interference is morally dubious not as such but when it is arbitrary and does not track common recognizable interests that individuals have *qua* citizens. I have, however, also concluded that the latter idea should not be acritically conflated with an overarching notion of population health that should prevail over individuals, presumably narrow, interests. I have, instead, emphasized that a public health policy is for the common good when it is able to let emerge all health shared interests, also those who are hold by minority groups.

In the second chapter, instead, I have elaborated on the ways one can conceive of justice in public health. After having specified how I intended to deal with the increased recognition of health inequalities and their socially determined nature, I concluded by showing that justice in public health requires two things. The first requirement is a minimal injunction for public health policies not to worsen existing inequalities, what I called the negative aim of justice. The second requirement, instead, stems from Sen's capability approach and tells us that central focus of distribution in public health policies should not only be resources, but also capabilities to function.

The theoretical analysis of part 1 of the thesis allowed me to assess whether current policies make a correct balance of the three ethical trade-offs that I have identified emerging in the context of the third chapter. These trade-offs are those between individual choice v. population health, individual choice v. justice, and justice v. efficiency. As I have shown, all the three values part of the trade-offs have prima facie validity. Hence I have tried to understand, in the remaining part of the thesis, how current policies are facing with respect to them, and what values they give priority to.

In the fourth chapter I have explored the policy means adopted in the US, Italy and UK to control HPV infections and reduce the incidence of cervical cancer. I have noticed that all the models identified differently put in balance the moral concerns at stake in the issue. In particular, I have noticed that an insistence on the least restrictive alternative alone leaves out of focus important concerns for social justice and the need to avoid the worsening of existing inequalities. Although the contextual aspects of any policy have, clearly, to be taken into account, the school based programme looked as the one allowing broader space

for the recognition of all the interests at play. The general conclusion I drew from the comparison runs against one tenet of the beneficence model. Indeed, I have shown that the morally preferable policy alternative is not the one that enlarges the space for non-interfered choices - like the voluntary model in the US - but the one that, while still leaving vaccination voluntary, also offers the opportunity to enlarge the informational basis on which vaccination choices are made and that does it in a way that does not worsen existing inequalities. In this sense, I have specified that the school-based system – as performed in the UK - creates the space for respecting choice while effectively offering the vaccination opportunity to all individuals. In this sense, the school-based model also meets concerns for the negative aim of justice presented in the second chapter.

Although things are perhaps slowly changing as I write, HPV vaccination has long been framed as a woman's issue only. The reasons of this framing are partially due to historical contingencies – i.e. HPV control has been embedded in an established network of healthcare services in the context of cervical cancer prevention – and partially to the opportunity cost that extending the programmes to the male population would have. Nevertheless, in chapter five I have shown that basing public health policy decisions on issues of economic efficiency alone may come at a moral opportunity cost. I have illustrated how public health policies, besides their officially stated objective, carry with them also meanings that we may find morally undesirable. A female-only policy, I have argued, foster the invidious gender stereotype that women alone should take the burden of issues related to sexual health and prevention. Extending the programmes to the male population too, however, is not only justified by the expressive function of the policy. Including males into the programmes, indeed,

would allow the establishment of herd immunity effects to the benefit also of the people that for various reasons – often of socioeconomic disadvantage though – could not be immunized. Moreover, a gender-based campaign neglects the presence in our societies of homosexual choices and, given the data presented, that there may be high-risk groups also among males. A gender-based campaign risks to systematically disadvantaging a minority group of people only because their conditions are rare. I have thus concluded chapter five by claiming that strong moral reasons would support the creation of herd immunity in the HPV context. Indeed, a gender-neutral policy is the one that, among feasible alternatives, better meets the needs of all.

In the final chapter of the thesis I have tried to reframe the moral focus that we should have on public health policies, in general, and HPV policies, in particular. More specifically, I have criticized common views in public health ethics that see the discipline as merely investigating the means of policies, and never interrogating their ends. This deficiency, hence, obscures the moral salience of human diversity and why certain conditions are morally worrisome. In particular, I have argued, we should shift our moral and policy focus from resources and functionings to capabilities to function; that is, what people can do and be with the resources they are provided with. Capabilities are effective freedoms to achieve valuable functioning, if one so wishes. I have argued that if we expand our moral evaluative gaze to capabilities, then we add a second dimension for making fruitful comparisons both at the individual and population level, thus understanding which conditions are morally worrisome and which are not. By showing what this conception would imply, both at the individual and population level, I argued that HPV policies should primarily aim

at distributing and maximizing relevant capabilities, especially where those are lacking. In practical terms, this would imply – at a minimum – increasing HPV and cancer related preventive awareness. As a way of pragmatic conclusion, I have suggested that one way to maximize capabilities expansion for all in the HPV context is by considering school as appropriate places of capabilities distribution.

'An ounce of prevention is worth a pound of cure' popular wisdom says. In this thesis I have tried to elaborate what this popular dictum, certainly valid for personal conduct, implies when we translate it on the populational scale. Although important at the individual level, indeed, sustaining and promoting health is, essentially, a social endeavour. Virtually no one could be healthy without a range of governmental institutions, private and non-profit organizations, professional expertises, all providing services and support for avoiding disease and curing morbidity. Health protection, in other words, is not an individual issue only but a collective one. In this work, therefore, I have attempted to depict the ethical dimensions that delineate the interactions occurring among governmental institutions, socially situated groups and individuals that have moral stakes in that 'ounce'.

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